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6	IN RE OPIOID LITIGATION
	/ No. 400000/2017
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9	HIGHLY CONFIDENTIAL
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14	VIDEOTAPED DEPOSITION OF ANNA LEMBKE, M.D.
15	San Francisco, California
16	Thursday, January 16, 2020
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23	REPORTED BY:
24	LESLIE ROCKWOOD ROSAS, RPR, CSR 3462
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3 FOR THE PLAINTHE COUNTY OF NASSAU: 4 NAPPLARANCES Continued					
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1			4 NAPOLI SHKOLNIK PLLC		
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No.	_	/ No. 400000/2017	7 Melville, New York 11747		
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10 11 12 Videotaped deposition of ANNA LEMBKE, M.D., 13 taken on behalf of Defendants, at the law offices of 14 Lieff Cabraser Heimann & Bernstein, LLP, 275 Battery 15 Street, Suite 2000, San Francisco, California, beginning 16 at 8:06 A.M. and ending at 5:27 P.M., on Thursday, 17 January 16, 2020, before Leslie Rockwood Rosas, RPR, 18 Certified Shorthand Reporter No. 3462. 19 20 21 22 22 23 24 25 25 27 21 24 25 27 27 27 27 27 27 27		HIGHLY CONFIDENTIAL	1		
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2 3 FOR THE PLAINTIFF: 4 LIEFF CABRASER HIEMANN & BERNSTEIN, LLP 5 BY: DONALD C. ARBITBLIT, ESQ. 6 STEVEN M. PYSER, ESQ. 7 BRITT CIBULKA, ESQ. (via speakerphone) 7 725 Twelfth Street NW 8 275 Battery Street, Suite 2900 8 Washington, DC 20005 9 San Francisco, California 94111-3339 9 202.434.5421 10 mmooney@wc.com 11 darbitbli@lchb.com 11 spyser@wc.com 12 awolf@lchb.com 13 13 14 FOR THE DEFENDANT WALMART: 15 STATE OF NEW YORK, OFFICE OF THE ATTORNEY GENERAL 16 BY: ED OTOOLE, ESQ. (via speakerphone) 16 BY: EDWARD M. CARTER, ESQ. 17 325 John H. McConnell Boulevard, Suite 600 18 Mineola, New York 11501 18 Columbus, Ohio 43215-2673 19 516.248.3302 20 emcarter@jonesday.com 21 22 22 23 24 4 4 4 4 4 4 4 4		Page 3	Page 5		
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Page 14	Page 16
1 record. Microphones are sensitive and may pick up	1 Hiemann & Bernstein, on behalf of plaintiffs.
2 whispers, private conversations or cell interference.	THE VIDEOGRAPHER: Anyone else? Thank you.
3 (Telephonic interruption.)	Would the Certified Court Reporter please swear
4 THE VIDEOGRAPHER: Would all present in the room	4 in the witness.
5 please identify themselves and state whom they represent.	5 THE REPORTER: Would you raise your right hand,
6 Counsel.	6 please.
7 MR. MOONEY: Matthew Mooney, Williams &	7 You do solemnly state that the evidence you
8 Connolly, for CardinalHealth. And next to me is Steve	8 shall give in this matter shall be the truth, the whole
9 Pyser, also of Williams & Connolly.	9 truth and nothing but the truth, so help you God?
10 MR. EHSAN: Houman Ehsan, O'Melveny & Myers, on	10 THE WITNESS: Yes, I do.
11 behalf of Johnson & Johnson and Janssen.	11 THE REPORTER: Thank you.
12 MR. CARTER: Ed Carter for Walmart.	12 THE VIDEOGRAPHER: Counsel.
13 MS. SMITH: Kate Swift for Walgreens.	13 EXAMINATION
14 MR. PORTER: Luke Porter, Reed Smith, on behalf	14 Q. BY MR. MOONEY: Good morning, Dr. Lembke.
15 of AmerisourceBergen.	15 A. Good morning.
16 MS. VICARI: Angela Vicari from Arnold & Porter	16 Q. Before we get started, I just want to put on the
17 for ENDO Pharmaceuticals, Inc., ENDO Health Solutions,	17 record that on January 14th of this month, the Court
18 Inc., Par Pharmaceutical, Inc., and Par Pharmaceutical	18 entered a short form order that concerns the conduct of
19 Companies.	19 expert depositions, and I've spoken to your counsel here
20 MR. TSAI: Rocky Tsai, Ropes & Gray, for	20 and he assured me that he's aware of the order.
21 Mallinckrodt.	21 And so we've been instructed to place the order
22 MS. RIVERA: Maria Rivera from Kirkland & Ellis	22 from Justice Garguilo on the record, and so I'm going to
23 on behalf of Allergan Finance.	23 offer that as Exhibit 1 to your deposition.
24 MS. RODGERS: Megan Rodgers, with Covington &	Would you please state your name for the record.
25 Burling, on behalf of McKesson.	25 A. Anna Lembke.
Page 15 1 MS. LEIBELL: Martha Leibell of Morgan & Lewis	Page 17 1 Q. And you are a professor at Stanford University
2 for the Teva and Actavis generic entities.	2 School of Medicine; is that right?
3 MS. WOLF: Abby Wolf on behalf of plaintiffs.	3 A. Yes.
4 MR. ARBITBLIT: Don Arbitblit, Lieff Cabraser	4 Q. What is your current title at Stanford?
5 Hiemann & Bernstein, for plaintiffs.	5 A. I'm an associate professor. I'm medical
6 THE VIDEOGRAPHER: Is there anybody appearing	6 director of addiction medicine. I'm program director of
7 telephonically?	7 our addiction medicine fellowship, and I'm chief of our
8 MR. O'TOOLE: Yes. Leo O'Toole, from the Office	8 addiction medicine dual diagnosis clinic. I also have a
9 of the New York State Attorney General on behalf of	9 courtesy appointment in the Department of Anesthesia
10 plaintiff.	10 Pain.
11 THE VIDEOGRAPHER: Okay, Leo O'Toole? One more	11 Q. And how long have you taught at Stanford?
12 time, Leo.	12 A. I've been teaching at Stanford for over
13 MR. O'TOOLE: Leo O'Toole, from the Office of	13 20 years.
14 the New York State Attorney General, on behalf of	14 Q. And would you please briefly walk through your
15 plaintiff.	15 educational background.
16 THE VIDEOGRAPHER: Thank you.	16 A. I did my undergraduate at Yale University,
17 Next? Anyone else?	17 graduating summa cum laude, Bachelor's in humanities. I
18 MR. BADALA: Sal Badala Sal Badala from	18 then attended Stanford Medical School, where I graduated
19 Napoli Shkolnik on behalf of Nassau County.	19 with an M.D. in 1995.
THE VIDEOGRAPHER: Is that it? Thank you.	I then completed a residency in psychiatry in
21 MS. PINCUS: Lauren Pincus oh Lauren	21 2000 and did a fellowship in mood disorders in the early
22 Pincus, from Allegaert Berger & Vogel, on behalf of	22 aughts at the same time that I joined as junior faculty
23 defendant Rochester Drug Cooperative, Inc.	23 at Stanford, and I've been there on faculty at the
24 THE VIDEOGRAPHER: Anyone else?	24 university and the School of Medicine since that time.
as array by all the state of	25 0 A. J

Q. And you were retained by the plaintiffs to

25

MS. CIBULKA: Britt Cibulka, from Lieff Cabraser

25

Page 18 Page 20 1 provide an expert report in this litigation; is that Q. You've been paid more than \$20,000 by the 2 correct? 2 plaintiffs in the New York litigation so far; is that 3 A. That is correct. 3 correct? Q. And did you create such a report? 4 A. I'm not sure. A. Yes, I did. 5 Q. How much do you think you have been paid by the 6 plaintiffs in the New York litigation so far? Q. I'm going to show you what's been marked as 7 Exhibit 2 to your deposition. Would you please take a A. I think it is more than \$20,000 so far. 8 moment to look at it. Q. Now, you also submitted a report in the Federal 9 multi-district litigation; is that correct? A. (Witness complies.) 10 Q. Would you please identify what's been handed to 10 A. Yes, I did. 11 you as Exhibit 2? 11 Q. Did the plaintiffs in the Federal opioid A. This is my expert report, which I submitted on 12 litigation also pay you for your time? 13 December 19, 2019, in this litigation. 13 A. Yes, they did. Q. And does the report that's been identified as 14 Q. The plaintiffs in the Federal opioid litigation 15 paid you more than \$200,000 for your opinions; is that 15 Exhibit 2 contain the opinions you intend to offer in 16 this litigation? 16 correct? 17 A. It's a long report so it's hard for me to assess 17 MR. ARBITBLIT: Objection to form. 18 whether it's exactly what I submitted, but I assume that 18 And just to clarify, is this a reciprocal --19 it is, and yes, it appears to contain my opinions. 19 have there been any agreements you're aware of as far as Q. I will represent to you that this is -- I 20 providing evidence on both sides as to what experts have 21 printed the PDF that we received from plaintiffs. So 21 been paid? Because if not, I'll object and instruct not 22 assuming that's true, does it contain the opinions you 22 to answer until there's -- there is an agreement. 23 intend to offer in this litigation? 23 MR. MOONEY: We received the expert -- or the 24 A. Yes. 24 invoices from Dr. Lembke's Federal District case -- or 25 Q. And does this report contain a comprehensive 25 Federal litigation. I'm just confirming that the numbers Page 19 Page 21 1 explanation of the opinions you intend to offer in this 1 that are on that invoice are what she was paid. 2 litigation? 2 MR. ARBITBLIT: I'll still object to the form of 3 A. It does contain my opinions, yes. 3 the question, but you can answer. 4 Q. And is it a comprehensive set of your opinions? THE WITNESS: I must admit I have not added it A. What do you mean by "comprehensive"? 5 up so I don't know the exact amount. Q. Well, are there other opinions that you didn't Q. BY MR. MOONEY: Can you provide an estimate of 7 offer in your report that you intend to offer in this 7 how much the plaintiffs paid you in the Federal 8 litigation for your opinion? 8 litigation? 9 A. No. 9 MR. ARBITBLIT: Object to form. 10 10 Q. When did the plaintiffs in this case retain you THE WITNESS: I really don't know. Q. BY MR. MOONEY: Have you received any other 11 as an expert? 11 12 MR. ARBITBLIT: Objection. Just to clarify --12 payments from plaintiffs in other opioid-related 13 and I won't do speaking objections, but we're going back 13 litigation? 14 to the MDL or do you mean New York? 14 A. Yes, I have. 15 MR. MOONEY: In New York. I'll clarify. Just 15 Q. Who -- who has paid you in other opioid 16 for everyone, I'll clarify when I'm talking about the 16 litigation? 17 Federal litigation. 17 A. The State of Washington. 18 18 THE WITNESS: I was first approached in November Q. And how much has the State of Washington paid 19 of 2019 to be an expert witness in this litigation. 19 you? 20 Q. BY MR. MOONEY: Are you paid by the hour? 20 MR. ARBITBLIT: Object to form. 21 A. Yes, I am. 21 And again, if there's reciprocal agreement that 22 O. What is your hourly rate? 22 all payments to defense experts are fair game and will be

23 answered, then I'll allow the witness to answer. If not,

And that goes for everyone around the table. If

25

24 I'll instruct her not to.

A. \$500 per hour.

A. \$800 per hour.

Q. And how about for your time testifying?

23

24

25

Page 22 Page 24 1 there's an agreement, she can answer; if there isn't, she 1 to every region in the country and readily dispensed. 2 won't. Q. What is the paradigm shift in the distributor 3 MR. PYSER: I'll jump in. This is Steven Pyser. 3 supply chain? 4 The question pending, we can talk off-line --A. The paradigm shift in the distributor supply 5 there's a lot of defendants -- about whether there's 5 chain is the collaboration between distributors and 6 pharmacies and opioid manufacturers that led to a massive 6 agreements across all of the cases. To my knowledge, 7 there's not. But there is no sound basis for an 7 increase in the number of pills, putting the population 8 objection here. 9 The question's pending. It's a simple question. Q. Do you have any expertise in supply chain 10 There's no basis not to -- to instruct not to answer. 10 management? 11 MR. ARBITBLIT: I disagree. We don't -- we 11 MR. ARBITBLIT: Object to form. 12 don't agree with that. 12 THE WITNESS: I am familiar with the path of 13 Don't answer. 13 opioid pills from manufacturers to distributors to 14 Q. BY MR. MOONEY: Turn to page 5 and 6 of your 14 pharmacies to patients. I've spent the last 20 years as 15 report. 15 a practicing physician. I've also researched the opioid 16 Dr. Lembke, are you going to follow your 16 epidemic. 17 counsel's advice not to answer the question? 17 And so based on that, I do have expertise in 18 A. Yes, I am. 18 understanding how that supply chain has contributed to 19 Q. On pages 5 and 6, you'll see a series of nine 19 the oversupply of opioids. 20 opinions. Q. BY MR. MOONEY: Have you ever worked in a 20 21 Do you see that? 21 pharmaceutical wholesale distributor? 22 A. Yes, I do. 22 A. No I have not. 23 Q. On page 6, paragraph 9: "Today's opioid crisis 23 Q. Have you ever worked in a pharmacy? 24 would not have occurred without the paradigm shift that 24 A. No, I have not. 25 contributed in overprescribing an excessive supply of 25 Q. Have you ever worked for a pharmaceutical Page 23 Page 25 1 opioids, which together contributed to the scourge of 1 manufacturer? 2 addiction and death." A. No, I have not. 3 3 Did I read that correctly? Q. Have you ever taken coursework in supply chain 4 A. No. 4 management? 5 Q. Would you read paragraph 9. 5 A. No. A. "Today's opioid crisis would not have occurred Q. Have you taken -- are you -- have you taken any 7 without the paradigm shift that resulted in 7 coursework relating to pharmaceutical distributors' 8 overprescribing an excessive supply of opioids, which 8 regulatory responsibilities? 9 together contributed to the scourge of addiction and 9 A. No, I have not. 10 death." 10 Q. Do you have any -- have you taken any coursework Q. And is it your opinion that today's opioid 11 regarding the wholesale distribution of controlled 11 12 crisis would not have occurred without a paradigm shift 12 substances? 13 that resulted in overprescribing an excessive supply of 13 A. No. 14 opioids? Q. Do you have any expertise concerning the 15 regulatory responsibilities rela- -- excuse me. Strike 15 A. Yes, that is my opinion. Q. When you say "the paradigm shift" in paragraph 16 16 that. 17 9, what are you referring to? 17 Do you have any expertise concerning the A. I'm referring to a change in our society leading 18 monitoring of suspicious orders by pharmacies? 19 to massive oversupply of opioids, putting the population A. I do have expertise in the sense that I am aware 19 20 at risk. 20 that the failure to scrutinize the distribution of opioid Q. And is that paradigm shift a paradigm shift in 21 pills in large volumes has contributed to the current

7 (Pages 22 - 25)

23

24

22 opioid epidemic.

Q. And what is that awareness based on?

25 being disseminated across this country, including to

A. That's based on reports of billions of pills

23

22 the treatment of pain?

A. That paradigm shift included both a shift in the

24 treatment of pain as well as an efficient distributor

25 supply chain that enabled those pills to be distributed

Page 26

- 1 small towns consisting of no more than 10,000 citizens,
- 2 amounts of pills that could never possibly be justified
- 3 by the need for analgesia in that community.
- 4 Q. Anything else?
- 5 A. It's also based on my clinical experience over
- 6 20 years observing the increased supply leading to ready
- 7 access, an endangerment of individuals due to that
- 8 increased supply, increasing their vulnerability to
- 9 addiction and accidental overdose death.
- 10 Q. Anything else?
- 11 A. Could you repeat the question?
- 12 Q. Anything else?
- 13 A. Could you repeat the root question?
- 14 Q. What is the -- what is your awareness of the
- 15 failure to scrutinize the distribution of opioid pills in
- 16 large volumes that has contributed to the opioid
- 17 epidemic?
- 18 A. My awareness also comes from reports that have
- 19 been issued on ARCOS data and DEA supply-chain data.
- Q. Anything else?
- 21 A. My awareness is also based on knowledge of pill
- 22 mills.
- Q. Can you identify any pill mills in the state of
- 24 New York?
- A. I'm not aware of any pill mills in the state of

1 So the NASEM report, which I refer to on page 12

Page 28

- 2 of my report, found that diversion is a key contributor
- 3 to increased exposure to prescription opioids, and I'm
- 4 quoting here from the NASEM report, quote: "DEA reports
- 5 that in recent years distributors in the United States
- 6 dispersed 12 to 15 billion dosage units of opioid
- 7 narcotics to retail-level purchasers, suggesting that
- 8 total diversion is on the order of 2.5 to 4 billion
- 9 dosage units," unquote.
- 10 Also a Washington Post analysis of Federal ARCOS
- 11 data shows that from 2006 to 2012, approximately
- 12 76 billion oxycodone and hydrocodone pills were delivered
- 13 in the United States.
- And if we were to assume the same rate of
- 15 diversion as from the NASEM report, that would represent
- 16 diversion on the order of 12 to 19 billion pills during
- 17 the six-year period from 2006 to 2012.
- 18 There was also a more recent Washington Post
- 19 report adding the years 2013 and 2014, bringing that
- 20 total number of disbursed pills up to 100 billion pills.
- 21 And that's based on ARCOS data.
- 22 Q. How many --
- 23 A. Oh, sorry. I was just going to say, I also base
- 24 my opinion on the impact of distribution on the opioid
- 25 epidemic on studies showing that in regions in the

- 1 New York.
- Q. Have you conducted any independent analysis
- 3 relating to the failure to scrutinize the distribution of
- 4 opioid pills in large volumes?
- 5 MR. ARBITBLIT: Object to form.
- 6 THE WITNESS: What do you mean by "independent 7 analysis"?
- 8 Q. BY MR. MOONEY: Well, you said that you're aware
- 9 of reports from ARCOS data or reports on the number of 10 pills that have been shipped.
- 11 My question is: Have you done any of your own
- 12 analysis to reach a conclusion about the distribution of
- 13 opioids?
- 14 A. I have not done my own numeric analysis of those
- 15 data.
- 16 Q. You were relying on what you have read in
- 17 newspaper reports?
- 18 A. Newspaper reports and other reports as well.
- 19 Q. Okay. What other reports?
- A. I'd like to refer to my report.
- 21 Q. Are you not familiar, sitting here today, with
- 22 the contents of your report?
- A. I'm very familiar, but this is a very serious
- 24 proceeding and I want to be as accurate as I possibly
- 25 can.

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 1 United States where more pills were disbursed were also
- 2 regions that saw increased rates of harm due to opioid,
- 3 including opioid addiction overdose deaths.
- 4 And I do refer to that in my report, and I'd
- 5 like to find that reference and also include it in my
- 6 response.
- 7 So on page 85 of my report, I talk about how
- 8 based on an article by Ghertner, et al., that: "ARCOS
- 9 data on opioid prescribing shows a 9-percent increase in
- 10 opioid hospitalizations for each 1 morphine kilogram
- 11 equivalent increase in opioid sales at the county level.
- 12 These data demonstrate a clear and convincing geographic
- 13 specific link between opioid dispensing and
- 14 opioid-related harm."
- 15 Q. Opioid prescribed -- this paragraph E references
- 16 opioid prescribing; is that right?
- 17 MR. ARBITBLIT: Object to form.
- 18 THE WITNESS: It references opioid sales at the
- 19 county level.
- Q. BY MR. MOONEY: In paragraph E of page 85:
- 21 "ARCOS data on opioid prescribing showing 9-percent
- 22 increase in opioid-related hospitalizations for each
- 23 1 morphine kilogram equivalent increase in opioid sales
- 24 at the county level."
- 25 Is that right?

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1 A. Yes, that's right.

- Q. And do you agree that opioid sales from a
- 3 pharmacy would not -- do not happen without a
- 4 prescription?
- A. Pharmacies also have a responsibility in the
- 6 opioid supply chain to make sure that patient consumers
- 7 are not being harmed by the opioids that are dispensed.
- 8 So although I would agree that pharmacies cannot dispense
- 9 opioids without a prescription, I would qualify that to
- 10 say that they also have a responsibility to patient
- 11 consumers to ensure that it's an appropriate prescription
- 12 and that it's a true prescription, it's not a
- 13 prescription that will harm the patient.
- Pharmacists do have a responsibility, for
- 15 example, to check drug interactions to check relative
- 16 contraindications.
- 17 Pharmacists play an important role in educating
- 18 their patients about the risks and benefits of the
- 19 medications they're dispensing. So pharmacists are not
- 20 merely in a passive role of turning over opioids or other
- 21 medications when they get a prescription. They have also
- 22 a health-safety relationship to their patients.
- 23 MR. CARTER: This is Ed Carter.
- 24 I move to strike everything in that response
- 25 other than "I would agree pharmacies cannot dispense

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- 1 opioids without a prescription."
- 2 MR. MOONEY: And I will just repeat the
- 3 question, understanding you have a caveat.
- Q. My question was -- was simpler: Do you agree
- 5 that opioid sales from a pharmacy do not happen without a
- 7 MR. ARBITBLIT: Object to form.
- 8 THE WITNESS: I agree, with the caveat stated 9 previously.
- 10 Q. BY MR. MOONEY: If you could turn to page 13 of
- 11 your report. Paragraph 2: "Opioid prescribing began --
- 12 began to increase in the 1980s, became prolific in the
- 13 1990s and the early part of the 21st century,
- 14 representing a radical paradigm shift in the treatment of
- 15 pain and creating more access to opioids across the
- 16 United States."
- 17 Did I read that correctly?
- 18 A. Yes, you did.
- 19 Q. Is that the opinion that you have in this case?
- 20 A. That is one of nine opinions that I have in this
- 21 case.
- 22 O. And so prior to 1980, doctors used opioid pain
- 23 relievers sparingly; is that right?
- 24
- 25 Q. And then there was a change in how doctors

- 1 prescribed opioids?
 - A. Yes.
 - Q. And you say that that change was radical?
- 4 A. Yes.
- 5 Q. What do you mean by there was a radical change

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- 6 in the way that doctors treated pain?
- A. Prior to 1980, doctors used opioids sparingly
- 8 for acute pain for people in extreme agony and at the end
- 9 of life. Starting in the 1980s, particularly in the
- 10 1990s, that paradigm changed such that opioids became
- 11 first-line treatment for even minor and chronic pain
- 12 conditions.
- 13 Q. Does that mean that a responsible physician
- 14 trying to act in good faith in treating his or her
- 15 patients would have prescribed opioids more often than in
- 16 the past?
- 17 MR. ARBITBLIT: Object to form.
- 18 THE WITNESS: What it means is that several
- generations of physicians were misled in terms of what
- 20 the science showed regarding safety and efficacy of
- 21 opioids, and in believing that they were prescribing
- 22 according to good science, they began to prescribe
- 23 opioids for minor and chronic pain conditions in a
- 24 departure from past practice.
- 25 Q. BY MR. MOONEY: And that departure was that

- 1 opioids would be prescribed more frequently than in the 2 past; is that correct?
- A. That's correct.
- Q. Is it your opinion that the change in medical
- 5 practice toward liberal opioid prescribing has been a
- 6 major factor contributing to the increased supply which
- 7 has fueled the opioid epidemic?
- A. It's my opinion that the change in opioid
- 9 prescribing has been a major factor, but not the only
- 10 factor. Another major factor has been an efficient
- 11 distributor supply chain as well as the problem of
- 12 diversion of opioids through various means.
- Q. Is it your understanding that pharmaceutical 13
- 14 distributors ship prescription drugs to pharmacies when a
- 15 pharmacy places an order for those drugs?
- 16 A. Yes, that is my understanding.
- 17 Q. Is it your understanding that pharmacies order
- 18 prescription drugs from distributors based on the
- 19 pharmacy's expected demand?
- 20 A. Yes, that's my understanding.
- Q. And in the case of prescription drugs, a
- 22 pharmacy's expected demand will depend on how many
- 23 customers come to the pharmacy with a doctor's
- 24 prescription for those drugs, doesn't it?
- 25 MR. ARBITBLIT: Object to form.

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THE WITNESS: I'm actually not that familiar

2 with what the pharmacies base their orders on.

3 Q. BY MR. MOONEY: Do you have any understanding of

- 4 pharmacy inventory management practices?
- 5 A. That's not my area, no.
- 6 Q. You keep referencing an efficient supply chain,
- 7 but no matter how efficient the supply chain is, without
- 8 a prescription, those pills are just going to sit on the
- 9 shelf, aren't they?

1

- 10 MR. ARBITBLIT: Object to form.
- 11 THE WITNESS: The efficient distributor supply
- 12 chain has played a major role in this epidemic. Without
- 13 the massive distribution of opioid pain pills to every
- 14 geographic region in the United States, this epidemic
- 15 would have been much less likely to occur and perhaps may
- 16 not have occurred at all.
- 17 So what your question assumes is that the
- 18 distributors are just innocently fulfilling orders, that
- 19 they're just the trucks, and that's not really an
- 20 accurate representation. Because they, too, have a
- 21 responsibility in scrutinizing suspicious orders and
- 22 being vigilant stewards of highly lethal drugs that
- 23 they're distributing and dispensing across the country.
- 24 Q. BY MR. MOONEY: These highly lethal drugs, these
- 25 are the opioids you're talking about?

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- 1 A. That's right.
- 2 Q. And those are FDA-approved drugs?
- 3 A. Yes, they are.
- 4 Q. And the FDA, even today in 2020, allows opioids
- 5 to be prescribed to patients; is that right?
- 6 A. Yes, it does.
- 7 Q. And is there anything about the efficient supply
- 8 chain that is unique to opioids as opposed to any of the
- 9 other numerous drugs that distributors distribute to
- 10 pharmacies?
- 11 MR. ARBITBLIT: Object to form.
- 12 THE WITNESS: Yes, I think so.
- 13 Q. BY MR. MOONEY: What is unique about the opioid 13
- 14 supply chain that makes it efficient?
- 15 A. One thing that is unique to the opioid supply
- 16 chain is the way that all of the actors from
- 17 manufacturers to distributors to pharmacies, benefitted
- 18 from the actions of the others in terms of increasing
- 19 demand and increasing supply.
- Q. How is that unique to opioids as opposed to any
- 21 other pharmaceutical product?
- A. Because in the case of opioids, there was
- 23 collusion around the fact that people were becoming
- 24 addicted and dying from these opioids, and yet the opioid
- 25 pharmaceutical industry turned the other cheek or turned

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- 1 a blind eye to that problem and sought to hide behind the
- 2 other and say it was somebody else's responsibility, when
- 3 in fact they all had a responsibility. But the money
- 4 was, you know, so appealing, that these various agencies
- 5 in the opioid distributor supply chain failed to meet
- 6 their stewardship responsibility vis-à-vis the American7 public.
- 8 Q. What's the basis for your statement that there
- 9 was collusion among the members of the supply chain?
- 10 A. One small example is I believe that some of the
- 11 distributors, for example, created coupons for free
- 12 samples of opioids that patients could get.
- 13 Q. Where is that in your report?
- 14 A. That is not in my report.
- 15 Q. Okay. What documents are you relying on to
- 16 support the belief that distributors created coupons for
- 17 free samples of opioids?
- 18 A. I've seen documents showing that McKesson
- 19 created coupons for free samples of Nucynta.
- Q. Anything else?
- A. No. But the practice of kind of promotional
- 22 efforts and free coupons and a general collusion between
- 23 these individuals is something that I feel I have seen in
- 24 my more than 20 years of medical practice.
- I would also add that opioids are unique from

- 1 other medications because of their highly addictive2 potential and their lethality and the fact that they
- 3 create a serious dependent syndrome that drives ongoing
- 4 use, even beyond utility or safety or efficacy.
- 5 So I do think that the pharmaceutical industry
- 6 that is involved in opioids has a responsibility above
- 7 and beyond what might be there even for other types of
- 8 medications that are not as addictive and not as lethal.
- O O W
- 9 Q. You say the money was so appealing. What's the 10 profit margin for opioids for a pharmaceutical
- 11 distributor?
- 12 MR. ARBITBLIT: Object to form.
 - THE WITNESS: I can't give you specific numbers,
- 14 but my sense is that it's a billion-dollar industry.
- 15 Q. BY MR. MOONEY: And what is that based on?
- 16 THE WITNESS: That's based on my reading in the 17 public domain.
- 18 Q. BY MR. MOONEY: And what are distributors'
- 19 profits from this so-called billion-dollar industry?
- 20 MR. ARBITBLIT: Object to form.
- 21 THE WITNESS: I'm not familiar with specific
- 22 numbers regarding profits.
- 23 Q. BY MR. MOONEY: So how do you know that the
- 24 money was so appealing that it caused the distributors to
- 25 look the other way?

A. Because I am aware that this is a

2 billion-dollar -- a multi-billion-dollar industry.

- Q. You also say that you said you think the
- 4 pharmaceutical industry that is involved in opioids has a
- 5 responsibility above and beyond what there might be even
- 6 for other types of medications. What do you mean by "a
- 7 responsibility above and beyond"?
- A. Opioids, in a sense, sell themselves because of
- 9 their addictive potential. So I believe that when it
- 10 comes to the opioid pharmaceutical industry, they need to
- 11 be especially vigilant about the problem of opioid
- 12 addiction overdose death beyond what they would need to
- 13 be for a non-addictive medication or even an addictive
- 14 medication that is not an opioid. I think opioids are
- 15 unique in this way.

1

- Q. And what would that especially vigilant, what
- 17 would that look like?
- 19 regarding regions of the country that -- and pharmacies

A. That would look like being very, very vigilant

- 20 that are ordering especially high volumes of opioids and
- 21 very closely scrutinizing those pharmacies in those
- 22 regions to determine whether or not diversion is
- 23 occurring or whether or not the citizens in that
- 24 community are being harmed by the opioids that they are
- 25 ingesting.

1

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- It would involve an additional degree of
- 2 scrutiny and vigilance and also caution such that if
- 3 there is a spike or an increase in a specific region in
- 4 terms of orders for opioid medication, then the opioid
- 5 pharmaceutical industry has a responsibility to have a
- 6 very high suspicion for a problem in that community along
- 7 the lines of addiction, either through a legitimate
- 8 prescription or addiction through diversion.
- Q. How is a distributor supposed to know if a
- 10 community is experiencing addiction through legitimate
- 11 prescriptions?
- 12 MR. ARBITBLIT: Object to form.
- THE WITNESS: The job of a distributor is to
- 14 assess suspicious orders. Suspicious orders are
- 15 determined in part by the volume of pills shipped to a
- 16 given region, a concern for pill mill doctors in that
- 17 region, a concern for diversion in that region.
- 18 So geographic spikes or increases in opioid
- 19 orders should be a concern for that community being
- 20 harmed by those opioids.
- It's not enough to say that, well, that's what
- 22 the doctor ordered. That's not sufficient. That reneges
- on their responsibility.
- Sorry, I said "reneges on their responsibility,"
- 25 not "renders."

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- Q. When there was a change in the way in which
- 2 doctors prescribed opioids, was that change limited to a
- 3 specific type of doctor?
- A. No, that was a paradigm shift across all medical
- 5 specialties.
- O. And by volume, did the family medicine doctors
- 7 and internal medicine doctors account for most of the
- 8 opioids that were prescribed?
- 9 A. Yes.
- 10 Q. And so as you analyzed it in your 2016 article,
- 11 was the problem of overprescribing the result of a small
- 12 number of especially big prescribers?
- A. The point of that 2016 article was to highlight
- 14 that the paradigm shift in treatment of pain in medicine
- 15 over the last three decades has led to all different
- 16 types of prescribers prescribing more opioids.
- 17 Q. And then --
- 18 A. None -- nonetheless -- nonetheless, pill mill
- 19 doctors, or small subsets of prolific prescribers, have
- 20 also contributed to the problem. They're not the only
- 21 explanation, but they are a part of the problem.
- 22 So it's both pill mill doctors and the broad
- 23 shift in prescribing that has led to the oversupply of
- 24 opioids in our communities.
- 25 Q. And that shift in prescribing, was that because

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- 1 there was a wholesale shift in the generally accepted
- 2 medical practice as it relates to the treatment of pain?
- A. Yes.
- Q. You also submitted a report in the Federal
- 5 multidistrict opioid litigation; is that correct?
- A. Yes, that's correct.
- Q. Is it fair to say that if you said something in
- 8 your earlier report but do not include it in your New
- 9 York report, then you do not intend to offer the earlier
- 10 opinion in this litigation?
- 11 MR. ARBITBLIT: Object to form.
- 12 THE WITNESS: Can you rephrase the question?
- 13 Q. BY MR. MOONEY: Sure.
- 14 So the opinion or the report that you submitted
- 15 in the New York litigation is not exactly the same as the
- 16 report that you offered in the Federal litigation; is
- 17 that right?
- 18 A. That's right.
- 19 Q. And so my question is: If there are
- 20 differences, and you said something in the New York
- 21 report -- or excuse me. Strike that.
- 22 If there are differences and you said something
- 23 in the Federal report and that is not included in your
- 24 New York report, can we assume that you do not intend to
- 25 offer the information -- the opinion that was only in the

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1 Federal litigation report?

- 2 A. I would not assume that. I have a very large
- 3 body of work that predates my involvement in any opioid
- 4 litigation, and my opinions are based on that body of
- 5 work, on my clinical experience, as well as my reports.
- 6 It's -- it's all of a piece.
- 7 Q. What opinions in your Federal report that are
- 8 not in your New York report do you intend to offer in
- 9 this case?
- 10 MR. ARBITBLIT: Object to form.
- 11 THE WITNESS: If you could refer to some
- 12 specific difference between the reports, it would be
- 13 easier for me to comment.
- 14 Q. BY MR. MOONEY: So sitting here today, you can't
- 15 identify opinions that were in your Federal report that
- 16 are not in your New York report that you intend to offer
- 17 in the New York litigation; is that correct?
- 18 MR. ARBITBLIT: Object to form.
- 19 THE WITNESS: The differences in the two reports
- 20 are largely structural. The opinions are the same.
- 21 Q. BY MR. MOONEY: You also gave a deposition in
- 22 the Federal litigation?
- 23 A. That's right.
- Q. And you were under oath?
- 25 A. Yes, I was.

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- 1 Q. Did you have a chance to review the transcript
- 2 after the deposition ended?
- 3 A. Yes, I did.
- 4 Q. Did you have a chance to make changes to your
- 5 testimony on an errata?
- 6 A. Yes, I did.
- 7 Q. Is there any statement in the Federal litigation
- 8 deposition that you now believe to be false?
- 9 A. No.
- 10 Q. So you stand by what you said in that sworn
- 11 testimony?
- 12 A. Yes.
- Q. Do you treat patients with chronic pain?
- 14 A. Yes
- 15 Q. Do you prescribe opioids to your patients?
- 16 A. Yes.
- 17 Q. Have you prescribed opioids to your patients
- 18 with chronic pain?
- 19 A. Yes.
- Q. How long have you been prescribing opioids?
- A. I've been prescribing opioids since I began my
- 22 medical training and my medical career in the mid-1990s.
- 23 I would qualify my positive response to say that the only
- 24 opioid that I prescribe now are opioids to treat opioid
- 25 addiction. I treat chronic pain, but I don't prescribe

1 opioids currently for the treatment of chronic pain.

- 2 Q. When you say that you only prescribe -- you
- 3 prescribe opioids now only to treat opioid addiction; is
- 4 that right?
- 5 A. That's correct.
- 6 Q. Is the reason you qualify it because that's a
- 7 change from your past practices with respect to
- 8 prescribing opioids?
- 9 A. My opioid prescribing for pain occurred mainly
- 10 when I was a medical intern and not in my psychiatric
- 11 practice. It's not within the scope of psychiatric
- 12 practice typically to prescribe Schedule II opioids for
- 13 pain.
- 14 The kind of treatment that I as a psychiatrist
- 15 administer for pain has to do with psychological and
- 16 mind-body interventions. I can certainly make
- 17 recommendations, and I am actively involved in helping
- 18 patients who have become dependent on or addicted to
- 19 opioids, but I do that in collaboration with their opioid 20 prescriber.
- That is a big part of my practice now, and my
- 22 medical expertise is counseling primary care doctors and
- 23 pain specialists, for example, on how to safely and
- 24 compassionately taper their patients down to a lower dose
- 25 of a Schedule II opioid or off of an opioid.

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- 1 Q. When did you stop prescribing opioids for
- 2 chronic pain?
- 3 A. In the early aughts, when I transitioned to a
- 4 primary psychiatric practice.
- 5 Q. When is the last time you prescribed an opioid
- 6 for pain?
- 7 A. I can't give you a specific date.
- 8 Q. Last year?
- 9 A. No, I have not prescribed opioids for chronic
- 10 pain for the last 15 to 20 years of my practice.
- 11 Q. When did you last recommend that a doctor
- 12 prescribe an opioid for a patient?
- 13 MR. ARBITBLIT: Object to form.
- 14 THE WITNESS: I have lots of conversations with
- 15 other healthcare providers around opioids and opioid
- 16 prescribing. Those are careful and nuanced conversations
- 17 that are based on the evidence, that are based on my
- 18 clinical experience, and on the unique situation of that
- 19 patient.
- 20 Sometimes that involves recommending continuing
- 21 an opioid for chronic pain at a given dose. Sometimes it
- 22 involves recommending tapering to a lower dose or
- 23 tapering off. It really depends on a specific patient
- 24 situation.
- 25 Although I will add that much of my work has to

Page 46 1 do with helping healthcare providers safely and

- 2 compassionately taper their patients down to safer doses
- 3 or off entirely because of the harm done by taking
- 4 opioids chronologically and because of the lack of
- 5 evidence that opioids work for chronic pain and can even
- 6 make pain worse through a process called opioid-induced
- 7 hyperalgesia.
- 8 MR. MOONEY: Move to strike that answer.
- 9 Q. Dr. Lembke, my question was when did you last
- 10 recommend that a doctor prescribe an opioid for a
- 11 patient?
- 12 MR. ARBITBLIT: Object to form.
- 13 THE WITNESS: That is a very general question.
- 14 So if you could be more specific about what opioid and
- 15 what kind of clinical scenario, I would be better able to
- 16 answer your question.
- 17 Q. BY MR. MOONEY: Sitting here today, you can't
- 18 tell me when you last recommended that a doctor prescribe
- 19 an opioid for one of your patients under any
- 20 circumstances?
- 21 MR. ARBITBLIT: Object to form.
- 22 THE WITNESS: No, that's not true. That's work
- 23 that I do in every clinic, and I see patients every week
- 24 in clinic. So the discussion around opioids, when to
- 25 prescribe, how much, whether to taper, how to taper,

- 1 A. That's right.
- 2 Q. You said you have had conversations with other
- 3 doctors on -- and provide recommendations as to whether

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- 4 their patients should continue to be treated with
- 5 opioids?
- 6 A. Yes.
- 7 Q. When was the last time you made a recommendation
- 8 that a doctor continue to prescribe patients opioids?
- 9 MR. ARBITBLIT: Object to form.
- 10 THE WITNESS: Tuesday.
- 11 Q. BY MR. MOONEY: So two days ago?
- 12 A. Yes.
- 13 Q. What pharmacy were the pills that you prescribed
- 14 filled at?
- 15 A. I have these conversations around opioid
- 16 prescribing and doing a risk-benefit assessment and
- 17 whether the patient's developed opioid dependence or
- 18 opioid addiction so often in my clinical practice and on
- 19 such a regular basis that I could not tell you. It's not
- 20 an isolated event in my work. So, therefore, a specific
- 21 pharmacy doesn't stand out to me.
- I can -- if it's helpful, I could list some of
- 23 the common pharmacies in my area, but I'm not sure.
- 24 Q. Which distributors fill the prescriptions that
- 25 you write?

- 1 opioids and opioids in the use of chronic pain, opioids
- 2 in the use of acute pain, opioids in the use of opioid
- 3 use disorder is a conversation I have on a regular basis
- 4 in my professional work.
- 5 Q. BY MR. MOONEY: So is it fair to say on a
- 6 regular basis, you make recommendations that doctors
- 7 continue to prescribe opioids for your patients?
- 8 MR. ARBITBLIT: Object to form.
- 9 THE WITNESS: As I said, I regularly have
- 10 discussions about whether opioids are indicated, how to
- 11 do a risk-benefit assessment, and what to do with the
- 12 opioid prescription.
- 13 The -- your question implies -- I guess I would
- 14 just, again, like clarification on your question because
- 15 I want to make sure that I answer it accurately.
- 16 Q. You said that in your -- in your work as an
- 17 addiction doctor --
- 18 A. And --
- 19 Q. As a psychiatrist.
- A. And somebody who treats chronic pain and has a
- 21 courtesy appointment in the Department of Pain and
- 22 Anesthesia at Stanford School of Medicine.
- Q. Right. You said that in the last 15 years, you
- 24 personally haven't prescribed opioids for chronic pain;
- 25 is that right?

- 1 A. I don't know.
- Q. If one of your patients told you that a pharmacy
- 3 couldn't fill a prescription for opioids because the
- 4 distributor wouldn't ship to that pharmacy, what would
- 5 you tell your patient to do?
- 6 MR. ARBITBLIT: Object to form.
- 7 THE WITNESS: It would really depend on the
- 8 specifics of that patient's circumstance.
- 9 Q. BY MR. MOONEY: If -- so what -- what would --
- 10 what would depend on the patient's circumstances?
- 11 MR. ARBITBLIT: Object to form.
- 12 THE WITNESS: The specific patient and where
- 13 they got their prescription and what it was for and
- 14 whether or not it was truly indicated and whether or not
- 15 their report was, in fact, accurate regarding whether or
- 16 not they were able to obtain that prescription for that
- 17 opioid.
- 18 Q. BY MR. MOONEY: And so if one of your patients
- 19 said that they couldn't fill a prescription for opioids
- 20 because the distributor wouldn't ship to that pharmacy,
- 21 and you went through all the circumstances of the patient
- 22 and you determined that this -- this patient needed
- 23 those -- those opioids, what would you tell the patient
- 24 to do?
- MR. ARBITBLIT: Object to form.

Page 50 THE WITNESS: Probably the first thing that I

2 would do would be to contact the pharmacy directly and

3 try to figure out what the circumstances were of their

4 not having that particular medication.

Q. BY MR. MOONEY: Have you ever contacted a

6 pharmacy to ask why they don't have a particular

7 medication that you prescribe?

8 A. Frequently.

1

9 Q. And what did they -- what -- what answers have

10 you received from pharmacies when you've made such calls 210

1 A. Sometimes it has to do with a prior

12 authorization. Sometimes it has to do with the fact that

13 they don't have it in stock. Sometimes it has to do with

14 the fact that it's at another pharmacy in their same

15 chain and they have to have it shipped over and that will

16 take a few days.

17 Sometimes it has to do with the fact that

18 they're concerned about a pattern of behavior that

19 they've seen in that particular patient, which makes them

20 reluctant to dispense.

21 Q. Have you ever consulted with a distributor about

22 any of the prescriptions that you've written in your

23 practice?

24 A. No.

Q. Will you tell me the last pain patient you wrote

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1 THE WITNESS: Opioids that I have prescribed 2 have been diverted, yes.

3 Q. BY MR. MOONEY: And the opioids that you have

4 prescribed that were diverted, how were they diverted?

5 A. They were diverted by patients to whom I gave a 6 prescription who then either sold or gave away the

7 medications that I prescribed to them.

8 Q. Did you report the diverted pills to the police?

A. No.

Q. Did you believe -- or excuse me, did you report

11 the person who diverted the pills to the police?

12 A. Most of my patients suffer from addiction, and

13 so their behavior is part of their disease of addiction,

14 and I don't see myself in a law enforcement role. My

15 primary obligation to my patients is to care for them

16 while also recognizing that I have a responsibility to

17 the public.

24

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So when that happens, I change my prescribing to

19 make sure that they don't have access to pills in the way 20 that they had access before.

Q. So diversion is not a crime when it's one of

22 your patients; is that right?

23 MR. ARBITBLIT: Object to form. Argumentative.

Don't answer that question.

Come up with a new one.

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1 a prescription for?

2 MR. ARBITBLIT: Object to form.

3 She's not going to give you specifics of her

4 patients. That's an invasion of confidentiality.

5 Don't answer it.

6 Q. BY MR. MOONEY: Will you accept your counsel's

7 advice?

8 A. That would be a violation of HIPAA for me to

9 refer to a specific patient. I would never do that.

10 Q. What if I told you that I represent a

11 distributor and I want to investigate your patients and

12 how they're using opioids; would you then give me the

13 name and medical records of your patient?

14 MR. ARBITBLIT: Object to form.

15 THE WITNESS: I would consult Stanford's legal

16 and determine whether or not I was in a position to have

17 to offer that, legally offer that information. I'm not a

18 lawyer so I would consult a lawyer. And I would have

19 first and foremost in my mind the care and

20 confidentiality of my patient, which is my primary

21 responsibility.

22 Q. BY MR. MOONEY: From the opioids that you've

23 prescribed, have any been diverted?

24 MR. ARBITBLIT: Object to form. Assumes facts

25 not in evidence.

1 Q. BY MR. MOONEY: Are you going to listen to your

2 counsel and not answer?

A. I feel like I've answered that question.

Q. The question is pending. Can you answer the

5 question or do you follow your counsel's advice not to

6 answer it?

A. I'm going to follow my counsel's advice not to 8 answer.

9 Q. Should doctors who know that medications they've 10 prescribed have been diverted lose their license?

11 MR. ARBITBLIT: Object to form.

12 THE WITNESS: It really depends on the specific

13 circumstance.

14 Q. BY MR. MOONEY: Do you agree that for a couple

15 of days to a couple of weeks, opioids are magical for the

16 treatment of pain?

17

MR. ARBITBLIT: Object to form.

18 THE WITNESS: I'm not sure I would use the term

19 "magical." Opioids can have benefit short-term. They

20 are a useful tool. I would never suggest that there's no

21 role for opioids in medical treatment, but every case is

22 unique. Opioids are very high risk, and even when

23 prescribed short-term, it's necessary to weigh the risks

24 against the benefits.

25 Q. BY MR. MOONEY: In your professional medical

Page 54 Page 56 1 experience, if a doctor prescribes prescription opioids A. Yes, I will. 1 2 for short-term therapy of three weeks, how many opioid Q. Last year, what percentage of your total 3 pills does the doctor prescribe? 3 compensation came from serving as an expert in opioid 4 MR. ARBITBLIT: Object to form. 4 litigation in the United States? THE WITNESS: It all depends on the specific A. I don't know. I haven't made that calculation. 6 circumstance on what the medical indication is. Q. Have any of the plaintiffs in an opioid Q. BY MR. MOONEY: Can you provide a range of the 7 litigation allowed you to fly on their private plane to 8 number of pills that would be prescribed in a three-week 8 attend any hearing? 9 prescription? 9 A. No. 10 MR. ARBITBLIT: Object to form. 10 Q. You said you've been paid approximately \$20,000 11 so far for the New York litigation; is that right? 11 THE WITNESS: I really wouldn't want to 12 prescribe a range of pills. I don't think that's useful. 12 MR. ARBITBLIT: Object to form. 13 I wouldn't -- every case is unique. There is such a THE WITNESS: Again, I haven't added it up so I 13 14 range of medical conditions, of patient circumstances. 14 don't know. Q. BY MR. MOONEY: Has the number of pills in a 15 Q. BY MR. MOONEY: How many hours have you spent 16 prescription for three weeks of opioids remained the same 16 working on the New York litigation? 17 over the past decade? 17 A. I haven't added it up. I don't know. A. There is huge variation opioid prescribing 18 Q. We were talking a little bit earlier about a 19 across the country. In some geographic regions, opioid 19 efficient supply chain. Strike that. 20 prescribing has decreased rapidly; in others, it has not. 20 Can you approximate how long you've spent 21 It really depends on which doctor. 21 working on the New York litigation? 22 Q. So it depends on the doctors, then? 22 A. I'm reluctant to approximate because I really 23 A. It continues to depend largely on the doctor, 23 don't know. I would really -- I have a record. I could 24 yeah. 24 add it up, but I -- I don't want to approximate and then 25 Q. Have you ever been to Suffolk County, New York? 25 be far afield from what it actually was. Page 57 Page 55 A. I have not. Q. So sitting here today, you can't provide an 1 2 Q. Have you ever practiced medicine in Suffolk 2 approximation of how much time you've spent; correct? 3 County? 3 A. I can easily provide the exact number if you'd 4 A. No. 4 like me to access those records. I kept very careful 5 5 documentation of the time that I spent. Q. Have you ever been to Nassau County, New York? 6 Q. Did you bring that time with you today? Q. Have you ever practiced -- have you ever been A. I did not. 8 licensed to practice medicine in the State of New York? Q. So sitting here today, you cannot approximate 9 9 how much time you've spent on the New York litigation? 10 MR. MOONEY: We've been going about an hour. Do A. That's correct. 10 11 you want to take a break? 11 Q. We talked about an efficient supply chain MR. ARBITBLIT: Sure. 12 earlier. Do you recall that conversation? 12 THE VIDEOGRAPHER: Going off the record, the 13 A. Yes. 14 time is 9:03 a.m. 14 Q. Is Amazon an efficient distribution supply 15 chain? 15 (Recess.) 16 THE VIDEOGRAPHER: Back on the record. The time 16 MR. ARBITBLIT: Object to form. 17 is 9:26 a.m. 17 THE WITNESS: I'd like to know how that question Q. BY MR. MOONEY: Dr. Lembke, all in, how much 18 is relevant. 19 have you been paid by plaintiffs in any opioid litigation Q. BY MR. MOONEY: That's not -- that's not a 19 20 in this country? 20 question that you get to ask. I asked a question. Do MR. ARBITBLIT: I'll object and instruct not to 21 you have an answer? 22 answer unless we get an agreement that this is 22 MR. ARBITBLIT: Object to form. 23 reciprocal. 23 Q. BY MR. MOONEY: Do you consider Amazon to be an Q. BY MR. MOONEY: Will you follow your counsel's 24 efficient distribution supply chain? 25 instruction? 25 MR. ARBITBLIT: Object to form.

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THE WITNESS: It does seem efficient.

- 2 Q. BY MR. MOONEY: Can you identify any public
- 3 statement that you made before April 2015 in which you
- 4 claimed prescription opioids were overprescribed?
- 5 A. Yes.

1

- 6 Q. When did you make that statement?
- 7 A. I published a New England Journal of Medicine
- 8 perspective on the opioid crisis.
- 9 Q. And when did you publish that perspective?
- 10 A. That was in 2012.
- 11 Q. And in that perspective, you said that
- 12 prescription opioids were overprescribed?
- 13 A. Yes, I did.
- 14 Q. Can you identify any earlier statements than the
- 15 2012 Journal of -- New England Journal of Medicine
- 16 perspective?
- 17 A. Prior to 2015, I was actively writing my book
- 18 Drug Dealer M.D., How Doctors Were Duped, Patients Got
- 19 Hooked, and Why It's So Hard to Stop, and I was also
- 20 teaching on the topic of the opioid problem and giving
- 21 lectures. So I was frequently making statements
- 22 regarding the oversupply and overprescribing of opioids.
- 23 Q. Can you identify any statements earlier than
- 24 2012 in which you said that prescription opioids were
- 25 overprescribed?

1

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- 1 So, you know, I've been working and studying
- 2 this problem since the early aughts so it's probable that
- 3 I made statements to the overprescribing of opioids prior
- 4 to 2012. But 2012 was a kind of a landmark paper that I
- 5 published in the New England Journal of Medicine on this
- 6 topic followed by many publications since then regarding
- 7 the overprescribing and the oversupply of opioids.
- 8 Q. You reference on page 13 of your report in
- 9 romanette II a 1954 study. And you quote the study as
- 10 saying: "Morphine is not the answer to chronic pain."
- Do you recall that study?
- 12 A. Yes, I do.
- 13 Q. Can you identify any article that you wrote
- 14 between 1996 and the present in which you cited that 1954
- 15 study?
- 16 A. No.
- 17 Q. In your report you write about a 2001 continuing
- 18 medication -- or continuing medical education course on
- 19 the treatment of pain that every licensed physician in
- 20 California was required to attend.
- 21 Do you recall that continuing medical education
- 22 course?
- A. Yes, I do.
- Q. So first off, what is a continuing medical
- 25 education course?

- A. Do you mean written statements, published
- 2 statements, or just statements in general?
- 3 Q. Let's start with published statements and then
- 4 we can turn to written statements or journal articles,
- 5 rather than any talks or lectures. Not for your
- 6 students, but public facing.
- 7 MR. ARBITBLIT: Object to form.
- 8 THE WITNESS: Let me take a look at my CV which
- 9 is in my report.
- 10 It's possible that I referred to the oversupply
- 11 of opioids in the chapter that I wrote for the Stanford
- 12 School of Medicine Handbook of Developmental Psychiatry
- 13 On Adolescents and Young Adult Substance Use Problems.
- 14 I'd have to refer to that document to verify that.
- 15 Q. My question was about overprescribing, not
- 16 oversupply.
- 17 A. It's possible that I referred to it in that
- 18 document. I'd have to go back and reference that.
- 19 It's possible that I made a reference to
- 20 overprescribing of opioids in a publication for addiction
- 21 in 2013, From Self-Medication to Intoxication, Time For a
- 22 Paradigm Shift.
- As I said, in 2012 in the New England Journal of
- 24 Medicine piece, Why Doctors Prescribe Opioids to Known
- 25 Opioid Abusers.

- Page 61 A. Continuing medical education is courses that are
- 2 required for physicians to take after they finish medical
- 3 school and after they finish residency, once they're in
- 4 practice, in order to ensure that they have the latest
- 5 evidence to inform their care of patients. Attending a
- 6 certain number of continuing medical education courses
- 7 per year is mandatory in order to maintain licensure.
- 8 Q. And continuing medical education courses, are
- 9 they sometimes called CMEs?
- 10 A. Yes, they are.
- 11 Q. Did you attend the 2001 CME on the treatment of
- 12 pain that every licensed physician in California was
- 13 required to attend?
- 14 A. Yes, I did.
- 15 Q. Where was that CME held?
- 16 A. That was held in Palo Alto, California.
- 17 Q. And how many people attended that event?
- 18 A. I don't know the exact number. It looks to be
- 19 in the thousands.
- Q. And who presented at that 2001 CME?
- 21 A. I don't recall specific presenters except for
- 22 some of my Stanford colleagues who presented at that CME
- Q. Were there any representatives from a
- 24 pharmaceutical distributor that presented at the 2001
- 25 CME?

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- 1 A. There probably were, but I don't recall any 2 specifics.
- 3 Q. Why do you say there probably were?
- 4 A. Because it is very common for the pharmaceutical
- 5 industry to financially support CME and also to have
- 6 booths or tables at these events to promote their
- 7 products. That's been the standard, unfortunately.
- 8 Q. My question was different. Were there any
- 9 representatives of a pharmaceutical distributor, not the
- 10 pharmaceutical industry, the pharmaceutical distributor,
- 11 that presented at the 2001 CME?
- 12 A. Not that I recall.
- 13 Q. You write in your report, page 23, paragraph
- 14 romanette V: "I recall that there was no accurate
- 15 presentation of the risks of opioids, and the messages
- 16 that were provided tracks the misconceptions described
- 17 above regarding overstatement of the benefits of
- 18 opioids."
- 19 Did I read that correctly?
- A. Yes, you did.
- Q. At the time you attended the CME in 2001, did
- 22 you do anything to alert the attendees of the event that
- 23 the information that was being provided that day was
- 24 inaccurate?
- 25 A. I was extremely early in my career. I was very

erv

- Page 63 1 junior in my institution, and I did not alert anybody
- 2 because at that time, I myself was buying into those
- 3 misrepresentations. I was the convinced or let's say
- 4 partially convinced recipient of those misleading
- 5 messages.
- 6 Q. Any time in the year after the 2001 CME, did you
- 7 do anything to alert doctors that you believed the
- 8 information that was provided about prescription opioids
- 9 was inaccurate?
- 10 A. The evolution in my thinking occurred over that
- 11 decade, from approximately the year 2000 or, let's say,
- 12 the late -- mid-to-late '90s. I was trained in -- I went
- 13 to medical school, as you know, in the 1990s, my
- 14 residency in the late 1990s, and the evolution in my
- 15 thinking occurred over that decade since my medical
- 16 training.
- 17 So I did not alert anybody because I was
- 18 experiencing an evolution in my own thinking, and a
- 19 growing concern and skepticism regarding the messaging
- 20 that I had been the recipient of in medical school, in
- 21 residency, and at continuing medical education courses.
- And as I read more in the literature and saw
- 23 patients, I began to realize that what I had been taught
- 24 was false.
- 25 Q. Coming back to the question. At any time in the

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- 1 year after 2001, did you do anything to alert doctors
- 2 that you believed the information that was provided at
- 3 the 2001 CME about prescription opioids was inaccurate?
- 4 A. Yes, I did.
- 5 Q. What did you do?
- A. I began in my lectures to medical students and
- 7 residents and colleagues to talk about the problem of
- 8 opioids, the fact that they were being overprescribed,
- 9 that we, as a healthcare community, had been sold a bill
- 10 of goods regarding their safety and efficacy, and that we
- 11 had a responsibility to our patients to do something
- 12 about that problem.
- 13 I -- and I also, as you know, then published an
- 14 article in 2012 in The New England Journal of Medicine
- 15 which directly addressed this problem, and some of the
- 16 origins, though not all of the origins, specifically in
- 17 order to alert my colleagues in the healthcare profession
- 18 about the problem of opioid overprescribing and the
- 19 inherent risks associated with it.
- And then I also began work on my book that was
- 21 ultimately published by Johns Hopkins University Press in
- 22 2016 that specifically addresses this opioid crisis.
- 23 My intention in writing the book was to educate
- 24 my colleagues and patient-consumers about this problem.
- Q. Let's try this one more time.

- 1 In the year after the 2001 CME, 2001 to 2002,
- 2 did you do anything to alert doctors that you believed
- 3 the information that was provided about prescription
- 4 opioids was inaccurate?
- 5 A. I probably did. Informally talking about with
- 6 colleagues, expressing my skepticism and concern, but
- 7 again, that was my beginning of my awareness of a problem
- 8 as I began seeing more and more patients who were
- 9 misusing, dependent on, and addicted to prescription
- 10 opioids.
- 11 So to answer your question, it wasn't something
- 12 that happened suddenly overnight. It was an evolution in
- 13 my thinking beginning in the late 1990s, early aughts.
- 14 So there's not a specific point, but as I became
- 15 concerned, yes, I regularly talked with colleagues. I
- 16 began to think about the problem and address the problem.
- 17 Q. Was the CME presented again in 2002 with similar 18 misinformation?
- 19 A. I don't know.
- 20 Q. What about in 2003?
- A. I didn't track that exact CME and whether it was
- 22 presented, but I know that it was a requirement in 2001
- 23 to complete a CME on pain, which was a very unusual
- 24 circumstance. There were very few mandatory CMEs across
- 25 all specialties.

Page 66 And so it was significant to me, even at the

- 2 time that I took the 2001 CME, that I was being mandated
- 3 as a psychiatrist to take a course on pain.
- 4 What I learned, through my work and my research
- 5 over the ensuing decade, is that even that requirement
- 6 was probably the result of the opioid pharmaceutical
- 7 industry and their lobbying efforts to create this
- 8 paradigm shift in the treatment of pain and to
- 9 disseminate their misleading messages to every kind of
- 10 medical specialist.
- 11 Q. Who required -- where did the -- where did the
- 12 requirement come from that doctors had to attend this
- 13 2001 CME?

1

- 14 A. It came from the California State Medical Board.
- 15 Q. Exhibit B to your report lists the materials you
- 16 considered in reaching your opinions in this litigation;
- 17 is that right?
- 18 A. Yes.
- 19 Q. And you tried to make sure that that list was
- 20 complete?
- 21 A. Yes, I did.
- 22 Q. It was missing a few documents; right?
- 23 A. Which documents are you referring to?
- Q. Well, last night your counsel provided us with a
- 25 supplemental list of materials you considered.
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- 1 Are you aware of that?
- 2 A. Yes.
- 3 MR. MOONEY: Okay. Handing you Exhibit 3 to
- 4 your report.
- 5 (Exhibit 3, Supplemental Materials Considered
- 6 List, Dr. Anna Lembke, marked for
- 7 identification.)
- 8 Q. BY MR. MOONEY: Which is the list of
- 9 supplemental materials considered that we received from
- 10 counsel last evening.
- Have you identified any other documents between
- 12 last night and this morning that should be on a list
- 13 of -- or a list of materials you considered in forming
- 14 your opinion?
- 15 A. No.
- 16 Q. And so if you considered a document in forming
- 17 your opinions that you offer in this case, you listed the
- 18 document on Exhibit B or the supplemental list that was
- 19 provided last night; correct?
- 20 MR. ARBITBLIT: Object to form.
- 21 THE WITNESS: My opinion has been informed by
- 22 the documents that I've reviewed as well as 20 years of
- 23 clinical experience and training.
- Q. BY MR. MOONEY: Right. If there are materials,
- 25 though -- setting aside your clinical training and your

- 1 clinical experience -- if there are materials that you
- 2 considered in forming the opinions that are in your
- 3 report, you listed them in Exhibit B or in the
- 4 supplemental materials considered list; is that correct?
- 5 A. To the best of my knowledge, that is correct.
- 6 Q. Did you consider any documents that were
- 7 produced by a distributor in this case?
- 8 A. I don't believe so. Except for the McKesson
- 9 Nucynta coupons, which I believe were created by
- 10 McKesson. Or at least by McKesson in collaboration with
- 11 Janssen.
- 12 O. When you use the term "pharmaceutical opioid
- 13 industry" in your report, are you using it to mean the
- 14 same thing you meant in the Federal litigation report?
- 15 A. I'm using it to mean opioid manufacturers,
- 16 distributors and pharmacies.
- 17 Q. And so are you meaning -- are you using it to
- 18 mean the same thing that you meant in your Federal
- 19 litigation report?
- 20 A. Yes.
- Q. On page 6 of your report, at Opinion 3 you
- 22 write: "The pharmaceutical opioid industry contributed
- 23 to the paradigm shift in opioid prescribing through
- 24 promotional materials and its use and manipulation of key
- 25 opinion leaders, continuing medical education courses,
 - Page 69

- 1 professional medical societies, a Federation of State
- 2 Medical Boards to the Joint Commission to convey
- 3 misleading messages about the safety and efficacy of
- 4 prescription opioids."
- 5 Did I read that correctly?
- 6 A. Yes, you did.
- 7 Q. What is a "key opinion leader"?
- 8 A. A key opinion leader is an individual with
- 9 influence in the medical community, often an academic of
- 10 prestigious standing, for example, a professor or a
- 11 clinic chief at a major university or medical center who
- 12 is then working as a paid consultant for a pharmaceutical
- 13 company to promote their messaging.
- 14 Q. Can you identify any payments to a key opinion
- 15 leader by CardinalHealth?
- 16 A. No.
- 17 Q. How about for McKesson?
- 18 A. No.
- 19 Q. Same question for AmerisourceBergen Drug
- 20 Corporation and Rochester Drug Co-op.
- 21 A. No.
- Q. When you say "the pharmaceutical opioid industry
- 23 used and manipulated key opinion leaders," are you
- 24 talking about distributors?
- 25 A. I'm talking about opioid manufacturers.

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- 1 Q. When you say "the pharmaceutical opioid industry
- 2 used and manipulated continuing medical education
- 3 courses," are you talking about distributors?
- 4 A. No.
- Q. When you say "the pharmaceutical opioid industry
- 6 used and manipulated professional medical societies," are
- 7 you talking about distributors?
- A. No.
- Q. When you say "the pharmaceutical opioid industry
- 10 used and manipulated the Federation of State Medical
- 11 Boards and the Joint Commission," are you talking about
- 12 distributors?
- 13 A. No.
- 14 Q. Can you identify any false or misleading claim
- 15 about opioids that was made by a pharmaceutical
- 16 distributor that has been named as a defendant in this
- 17 case?
- 18 A. No.
- 19 Q. Of the oxycodone and hydrocodone pills dispensed
- 20 in the United States, what percentage were prescribed by
- 21 a doctor and filled by a patient?
- 22 MR. ARBITBLIT: Object to form.
- 23 THE WITNESS: I refer to my report, page 12, the
- 24 NASEM report, based on DEA reports noting 76 billion
- 25 oxycodone and hydrocodone pills delivered in the

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- 1 United States, with 12 to 19 billion pills diverted.
- 2 Diversion can occur at multiple levels prior to a doctor
- 3 prescribing it or a pharmacy receiving it, at the time of
- 4 prescription and also after the prescription. So it's
- 5 extremely hard to estimate.
- MR. MOONEY: Move to strike.
- Q. But what percentage of -- of the oxycodone and
- 8 hydrocodone pills dispensed in the United States, what
- 9 percentage were prescribed by a doctor and filled by a 10 patient?
- 11 MR. ARBITBLIT: Object to form.
- 12 THE WITNESS: The majority, but I don't know the
- 13 exact percent.
- Q. BY MR. MOONEY: And of the percentage of opioids
- 15 that are prescribed by a doctor and filled by a patient,
- 16 what percentage of those pills were pursuant to illegal
- 17 prescriptions?
- 18 MR. ARBITBLIT: Object to form.
- THE WITNESS: Very hard to quantify that. It 19
- 20 would really depend on what you mean by an illegal
- 21 prescription.
- O. BY MR. MOONEY: What percentage of doctors'
- 23 prescriptions for opioids are not for legitimate medical
- A. Again, I think that the question doesn't really

1 appreciate the complexity of the problem. Patients who

- 2 receive a prescription for a legitimate medical purpose
- 3 can go on themselves to be addicted to that opioid. They
- 4 can also divert a portion of their legitimate
- 5 prescription to others who are then harmed.
- That diversion may occur intentionally or
- 7 unintentionally, for example, a teenager getting pills
- 8 from a grandparent's medicine cabinet without the
- 9 awareness of that individual who has the legitimate
- 10 prescription.
- 11 Then there are individuals who intentionally
- 12 seek out a doctor for the purpose of obtaining pills for
- 13 non-legitimate medical purposes.
- 14 So it's very difficult to answer that question
- 15 simply. It's a complicated question. It's a complicated
- 16 situation, and I don't think we even now fully know
- 17 accurately of the rates of diversion. We have estimates,
- 18 but...
- 19 Q. I understand that diversion can occur after the
- 20 prescription is filled and it can occur in other places,
- 21 too.
- 22 My question is: What percentage of doctors'
- 23 prescription of opioids are not for legitimate medical
- 24 purposes?
- 25 MR. ARBITBLIT: Object to form.

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- THE WITNESS: How would you define "legitimate 1 2 medical purposes"?
- Q. BY MR. MOONEY: As a doctor, do you have
- 4 responsibilities to ensure that your patients -- or that
- 5 you prescribe medications for patients that are for
- 6 legitimate medical purposes?
- A. Yes, we do. But if we've been misinformed about
- 8 what a legitimate medical purpose is, then we may
- 9 prescribe believing that we're engaging in a legitimate
- 10 prescription, when in fact, that prescription may not be
- 11 what is helpful to that patient.
- 12 Q. What percentage of doctors' prescriptions for
- 13 prescription opioids are for a legitimate medical
- 14 purpose, assuming that it is done with the belief that
- 15 they are engaging in appropriate medical care?
- MR. ARBITBLIT: Object to form. 16
- 17 THE WITNESS: The majority of opioid
- 18 prescriptions are for a legitimate medical purpose, but I
- 19 couldn't quantify it. I just believe that the majority
- 20 of doctors are well-intended and trying to help their 21 patients.
- 22 There are doctors who have lost their moral
- 23 compass and are prescribing opioids knowing that their
- 24 patient shouldn't get those opioids, and that subset is a
- 25 part of this problem, but another large part of this

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1 problem is well-intended doctors who believe they are
2 prescribing opioids for legitimate purposes but have been
2

3 misinformed and miseducated due to defendants' actions.
 4 Q. What percentage of opioid medication prescribed

- 5 by a doctor and dispensed by a pharmacy sits unused in a 6 patient's medicine cabinet?
- 7 MR. ARBITBLIT: Object to form.
- 8 THE WITNESS: There are data coming out now
- 9 showing that a large percentage of opioids that are
- 10 prescribed by a doctor are not, in fact, used by the
- 11 patient, especially in the postoperative setting. These
- 12 are data that are now being used to inform how opioids
- 13 should be prescribed postoperatively.
- What the studies are showing -- and I do cite
- 15 them in my report, and I can go to that place, if you'd
- 16 like -- are that as healthcare providers are cutting back
- 17 on opioid prescriptions, they're finding that their
- 18 patients are reporting no increases in pain, no increases
- 19 in calls for refills, and that they have fewer opioids
- 20 left sitting around in medicine cabinets for teenagers or
- 21 neighbors or whoever it is to come and take those
- 22 opioids. So --
- 23 Q. BY MR. MOONEY: Do you -- sorry. Go ahead.
- A. So my point being that with the growing
- 25 awareness of the opioid epidemic and research that is

1 getting opioid pills from their friends at school,

2 leftover prescriptions or from somebody at school who had

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- 3 pills who sold or gave it to them.
- 4 So what I saw over the first several decades of
- 5 this century was a growing number of patients who were
- 6 telling me that opioids were everywhere, that they were
- 7 easy to get, that you could ask a friend or you could
- 8 find a dealer, you know, one text message away, or you
- 9 could go see a doctor and easily obtain them.
- 10 Again, some of these were individuals who were
- 11 intentionally seeking out opioids for recreational use
- 12 and other of them were pain patients who themselves were
- 13 becoming addicted through their legitimate prescription.
- 14 I've also spent much of the last five years
- 15 traveling around the country, all over the country,
- 16 talking to doctors, trying to educate them about this
- 17 problem, urging them to prescribe opioids more
- 18 judiciously. And in that process, I've had many
- 19 conversations with doctors who have expressed that they
- 20 were duped by the pharmaceutical industry, that they
- 21 engaged in a very liberal prescription pad in terms of
- 22 prescribing opioids, and that they were looking back on
- 23 that practice with regret.
- 24 Interestingly, I was in Buffalo last year to
- 25 give a conference, to give a talk on the opioid epidemic

- 1 studying the extent of the harm, we are finding out that
- 2 a lot of patients are using some of their prescription
- 3 and leaving the rest to either be stolen, or in some
- 4 cases, they themselves may be diverting part of their
- 5 prescription or selling part of their prescription.
- 6 Q. And when did that growing awareness begin?
- 7 MR. ARBITBLIT: Object to form.
- 8 THE WITNESS: That growing awareness on my part?
- 9 Q. BY MR. MOONEY: Sorry. Go ahead.
- 10 A. That began for me in the early 2000s, as I
- 11 started seeing more and more patients coming into my
- 12 office reporting that they were misusing or addicted to
- 13 opioids. When I asked them where they got those opioids,
- 14 many of them reported that they got the opioids from a
- 15 doctor.
- Many of them actually believed that they were
- 17 taking the opioids in part for a legitimate pain
- 18 condition but also expressed concern that they were
- 19 becoming addicted through that legitimate prescription.
- 20 I also began seeing more and more patients in
- 21 the early aughts and beyond reporting that they had
- 22 increased easy access to prescription opioids from
- 23 friends and family members, left over opioids in medicine
- 24 cabinets.
- 25 I had teenagers coming in saying they were

- 1 to doctors, and one of the doctors came up to me
- 2 afterward and said that in her clinic, which was a clinic
- 3 for gynecologic cancer -- she had been in practice more
- 4 than 15 years -- they had instituted a new policy of
- 5 getting urine drug screens in their long-time opioid
- 6 chronic pain patients.
- 7 And to her shock and dismay, they discovered
- 8 that a large percentage of those patients had a urine
- 9 drug screen that was negative for opioids, the
- 10 implication being that individuals to whom they had been
- 11 giving what they thought were legitimate prescriptions
- 12 for many years, that those individuals were not, in fact,
- 13 taking the opioids that they were prescribing.
- 14 So through these many types of conversations, my
- 15 own clinical experience, and my reading in the
- 16 literature, I have seen what I have called in my report
- 17 the tsunami effect, the rising tide, the increased
- 18 supply.
- 19 And as an addiction medicine specialist, I know
- 20 that one of the biggest risk factors for developing
- 21 addiction is access to the drug. If you live in a
- 22 neighborhood where drugs are sold on the street corner,
- 23 you're more likely to try that drug and you're more
- 24 likely to get addicted to that drug.
- We've been living in a society for the past

HIGHLY CONFIDENTIAL Page 78 Page 80 1 30 years where opioids are readily available to anybody 1 after "in the early 2000s." 2 who wants them. And as a direct result of that increased Q. For the medical community at large, when did the 3 supply and exposure, we now have an opioid epidemic of 3 growing awareness of the opioid epidemic begin? 4 addiction and death on our hands. 4 MR. ARBITBLIT: Object to form. 5 Q. Dr. Lembke, do you have Exhibit 1 in front of THE WITNESS: In 2011, the CDC issued a warning 6 you? 6 that we were in the midst of a prescription drug 7 A. Exhibit 1. 7 epidemic, and they, in their warning, clearly stated that 8 8 the case was increased prescribing of opioids and other Q. It might be under your report. The copy that I 9 used --9 psychotropic medication. 10 A. This? 10 I think that that was a very important missive O. No, the Court's order. 11 11 and an important year that contributed to a growing 12 A. Yes, I do. 12 public awareness around the opioid epidemic. 13 Q. Okay. Now, were you made aware of this Court Following that, there were increasing numbers of 14 order before your deposition today? 14 reports in the media and in the lay press that I think 15 A. Yes, I was. 15 also helped the growing awareness, the public awareness. 16 16 Q. And so you know that Justice Garguilo entered an I can say that approximately two years ago, for 17 order that said in paragraph 1: "Your role as an expert 17 the first time in my professional career, I started 18 is not one of advocacy. Your role is to listen to the 18 seeing chronic pain patients coming in asking for help to 19 question and answer the question. You are not to comment 19 get off of their opioids, that they had heard that 20 on anything beyond the information sought within the 20 opioids were dangerous, that they had been on them for a 21 question." 21 long time, and that they wanted to get off. 22 Did I read that correctly? 22 That, to me, was evidence of the slow shift and 23 23 a growing awareness, when patients themselves were coming A. Yes, you did. 24 Q. Now, before you started answering my question --24 in saying, I read this article in the newspaper, or I 25 the question that was pending before your monologue: 25 heard this on the radio that opioids are dangerous and I Page 79 Page 81 1 "When did that growing awareness begin?" That's a time 1 didn't know that, and I'd like to get off. 2 question, is it not? Q. BY MR. MOONEY: Do you have an opinion on the 3 A. (Nods head.) 3 steps distributors could take to prevent unused medicine 4 MR. ARBITBLIT: Object to form. 4 from doctors' prescriptions from sitting unused in THE WITNESS: Because my growing awareness as 5 people's medicine cabinets? 6 implied by the word "growing," growing is something that MR. ARBITBLIT: Object to form. 7 7 happens gradually over time. Things don't grow in a THE WITNESS: I think that anything the opioid 8 second or a day, I felt that in order to accurately 8 pharmaceutical industry can do to limit the supply of 9 answer your question, I needed to explain the growth of 9 opioids to just what is evidence-based use of those 10 my awareness over the time period during which it 10 opioids would help reduce the number of pills sitting in 11 people's medicine cabinets. 11 occurred. 12 Q. BY MR. MOONEY: The information sought within 12 Q. BY MR. MOONEY: If distributors provided 13 the question, "When did it begin," you said, "It began

14 for me in the early 2000s." That's an answer to when;

15 correct?

16 A. It is a partial answer to when. If one's

17 growing awareness -- and those were your words, "growing

18 awareness," a growing awareness occurs over a longer

19 period of time, or at least my growing awareness occurred

20 over a longer period of time. And my response was my

21 best effort to thoroughly and accurately answer your

22 question.

23 MR. MOONEY: All right. We have a limited

24 amount of time with you so I'm not going to argue with

25 you on this any more, but I move to strike everything

13 20 percent less opioids across the board to all

14 pharmacies and hospitals, would that help with the

15 epidemic?

MR. ARBITBLIT: Object to form. 16

17 THE WITNESS: I'm not in a position to opine on

18 exact percentages or numbers. There are other experts

19 who will be weighing in on the -- on the role of

20 distributors who possibly could answer that, but that's

21 not a question that -- that I'm in a position to answer.

22 O. BY MR. MOONEY: How would a pharm- -- if

23 distributors provided 20 percent less medication across

24 the board to pharmacies and hospitals, how would those

25 pharmacies and hospitals decide which patients'

Page 82 1 prescriptions to fill and which ones should not be

2 filled?

3 MR. ARBITBLIT: Object to form.

- THE WITNESS: The question is a hypothetical. I
- 5 am uncomfortable with a specific number of 20 percent.
- 6 But I would say that the bottom line is that pharmacies
- 7 and hospitals should fill prescriptions that are based on
- 8 evidence-based medicine, with careful scrutiny as to
- 9 whether or not the individual and the community is being
- 10 harmed by the way in which those prescriptions are being
- 11 filled. So everybody has responsibility.
- 12 Q. BY MR. MOONEY: Including doctors?
- 13 A. Including doctors, yes.
- 14 Q. What would you -- what would a pharmacist need
- 15 to know to determine which prescriptions to fill and
- 16 which ones should not be filled?
- 17 MR. ARBITBLIT: Object to form.
- 18 THE WITNESS: Even now, pharmacists are checking 18 defendants' actions, including distributors and
- 19 the prescription drug monitoring database to see if the
- 20 patient is engaged in so-called doctor shopping or
- 21 whether or not there's dangerous co-prescribing, such as
- 22 combing opioids and benzodiazepines or opioids and other
- 23 sedatives.
- 24 A pharmacist should also have some familiarity
- 25 with that doctor and their general practice and whether

1 Nassau or Suffolk County?

- A. By shipping large numbers of pills very
- 3 efficiently so that pharmacies were heavily stocked with

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- 4 these pills, Suffolk County, along with the rest of the
- 5 United States, was heavily impacted.
- Q. Right. My question, though, is: How did the
- 7 distribution campaign affect the rates at which doctors
- 8 prescribed opioids in Nassau and Suffolk County?
- A. I refer to this in my report. I'd like to go to 10 that spot.
- 11 Okay. So between -- as I say on page 89 of my
- 12 report: "New York State data show a four-fold increase
- 13 in opioid mortality in the 25 to 44 age group from 2010
- 14 to 2016." And that includes Suffolk County.
- 15 So that increase in addiction among young adults
- 16 is a result of the increased supply of opioids in that
- 17 community, and the increased supply is a result of
- 19 pharmacies.
- 20 MR. MOONEY: Move to strike.
- 21 Q. Dr. Lembke, my question was: In what way did
- 22 the distribution campaigns impact the rates at which
- 23 doctors prescribe opioids in Nassau and Suffolk County?
- 24 A. Let me give you a corollary example. I saw a
- 25 patient last week with alcohol abuse disorder, and I

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1 or not they are practicing in a responsible way.

- The pharmacist should also be aware of the CDC
- 3 guidelines that are recommending that opioids not be used
- 4 as first-line treatment for pain and that doses for acute
- 5 pain be limited.
- Pharmacists should also just have good old
- 7 common sense, and if they're observing somebody who is
- 8 clearly impaired or intoxicated, along the lines of
- 9 somebody who may be misusing or addicted to opioids, that
- 10 should also play into their decision making.
- 11 For example, I have had pharmacists call me, and
- 12 even though I wrote a legitimate prescription for what I
- 13 believed was a legitimate medical indication, they have
- 14 called me and said, you know, I'm concerned about this
- 15 patient, she's presenting in a way that makes me think
- 16 she's intoxicated, and she's getting prescriptions,
- 17 multiple prescriptions from, you know, other providers.
- 18 Also, I have this history with this particular patient
- 19 prior to her being your patient, and so I know that she
- 20 has had X, Y or Z problem.
- These are all emergent, relevant, health-related
- 22 details that need to be communicated between everybody in 22
- 23 the opioid supply chain.
- Q. BY MR. MOONEY: In what way did prescription
- 25 opioid distribution campaigns impact prescribing rates in

Page 85 1 prescribed Antabuse disulfiram to him, and he was not

- 2 able to obtain that medication from several different
- 3 pharmacies in the area. I'm not sure why. So,
- 4 therefore, we thought about a different or alternative
- 5 medication.
- So if I'm practicing in a region where every
- 7 single opioid formulation under the sun is readily
- 8 available at every single pharmacy, and that becomes the
- 9 normative way to address pain, that is -- this is an
- 10 example of how distributors have impacted the rates at
- 11 which doctors describe opioids.
- 12 Q. What percentage of prescriptions for opioids are
- 13 due to a doctor's decision to provide a different or
- 14 alternative medication because the medication that they
- 15 want to provide is not available?
- 16 MR. ARBITBLIT: Object to form.
- 17 THE WITNESS: I guess I don't really understand
- 18 the question.
- 19 Q. BY MR. MOONEY: Well, I didn't understand your
- 20 answer before because I asked about Nassau and Suffolk
- 21 County.
- But what I understood you to mean was when you
- 23 thought about prescribing a different or alternative
- 24 medication that wasn't available, you thought about
- 25 providing something else; right?

Page 86 Page 88 1 right? 1 A. (Nods head.) Q. And then you said: "If I am practicing in a 2 A. Yes. 3 region where every single opioid formulation under the Q. And the third one is diversion after the 4 prescription has been filled, for example, by subsequent 4 sun is ready available" -- "readily available at every 5 single pharmacy, and that becomes the normative way to 5 transfer or sale to a third party; is that right? 6 address pain, that is an example of how distributors have A. Yes. Yes, that's right. 7 impacted the rates at which doctors prescribe opioids." Q. Do you agree that after a prescription for an Is that the gist of what you said? 8 opioid has been filled, a pharmaceutical distributor no 8 9 9 longer has control over what happens to those dispensed A. Yes. 10 Q. So my question is: Taking your corollary 10 drugs? 11 example about an alcohol -- a patient suffering from 11 MR. ARBITBLIT: Object to form. 12 alcoholism in California, what percentage of 12 THE WITNESS: I think that a distributor has 13 prescriptions are written for opioids in Nassau or 13 responsibility regarding the diversion of an opioid pill 14 Suffolk County because the doctor wasn't able to get the 14 after it's been filled. 15 other drug that he or she wanted because it was 15 Q. BY MR. MOONEY: My question was different: 16 unavailable at the pharmacy? 16 After the pharmaceutical opioid has been dispensed --17 A. I don't --17 A. Uh-huh. 18 MR. ARBITBLIT: Object to form. 18 Q. -- do you agree that the distributor no longer 19 THE WITNESS: I don't know. 19 has control over what happens to the drugs? Q. BY MR. MOONEY: Are you offering on opinion on 20 MR. ARBITBLIT: Object to form. 21 the appropriate number of pills that should have been 21 THE WITNESS: What do you mean by "control"? 22 distributed in the State of New York? Q. BY MR. MOONEY: After one of your patients fills 22 23 A. No. 23 a prescription for opioids, can CardinalHealth go to 24 Q. You've talked a couple of times about the NASEM 24 their house and take the unused medication out of their 25 report on page 12 of your report. 25 closet? Page 87 Page 89 1 A. (Nods head.) 1 MR. ARBITBLIT: Object to form. Q. And you referenced in romanette III that there 2 THE WITNESS: No, but what CardinalHealth can do 3 are several ways that prescription drugs are diverted to 3 is note suspicious orders or regions in which there is a 4 non-medical use. 4 heavy volume of pills not justified by the need for Do you recall writing that in your report? 5 analgesia in that community and investigate. 5 MR. MOONEY: Move to strike everything after 6 7 7 "no." Q. And the first example you give is diversion 8 before a prescription has been filled, for example, theft Q. Do you have a basis to offer an expert opinion 8 9 from production facilities or retail pharmacies; is that 9 in this case that pharmaceutical distributors have the 10 right? 10 ability to control what happens to prescription opioids 11 11 after they have been dispensed pursuant to a doctor's A. That's right. Q. Are you offering any opinion about any theft 12 prescription? 13 from a distributor in this case? 13 A. Again, I think I answered that. I think those 14 14 things are tied. I think a distributor has a Q. What percentage of diverted opioids are due to 15 15 responsibility to track what happens to the prescription 16 after it's been dispensed, and in the case of finding a 16 theft from a distributor? 17 A. I don't know. 17 suspicious or concerning situation, to intervene. 18 Q. Can we agree that actual -- can we agree that 18 Q. In your own medical practice, have you ever 19 actual theft is rare? 19 reported to a distributor which medications you've 20 A. I wouldn't agree to that because I have nothing 20 prescribed and to whom? 21 to base that on. 21 A. No. Q. The second version -- the second form of 22 O. Why not? 23 diversion in your report that you reference is diversion 23 A. That's just not something I've ever done. 24 24 via filling a prescription, for example, pursuant to Q. Why not? 25 25 doctor shopping and high-frequency prescribers; is that A. For the most part, I track my patients and their

HIGHLY CONFIDENTIAL Page 90 Page 92 1 use of the opioids that I prescribe extremely closely, 1 of addiction and overdose death, and the specifics of the 2 such that if there is diversion of any sort, it's very 2 distributors responsibility from a legal perspective is 3 minimal. I catch it within the week because of the way 3 something that other experts will opine on. Q. So you don't have a proposal in your report as 4 that I practice, and so I'm able to take care of that 5 situation. 5 to how a distributor is supposed to track individual 6 prescriptions after they've been dispensed; is that 6 And that is not, by the way, the standard of 7 care or it has not been the standard of care. We're 7 correct? 8 trying to change that. That's not the way that opioids A. That's correct. Q. You said that you've never provided prescription 9 are commonly being prescribed and monitored. 10 Q. Of the three types of diversion that you list in 10 information to a distributor. Have any of your 11 romanette III on page 12, only one diversion before the 11 colleagues at Stanford? 12 prescription is filled can occur when a distributor is in 12 MR. ARBITBLIT: Object to form. 13 physical possession of the prescription opioids; is that 13 THE WITNESS: I don't know. 14 right? Q. BY MR. MOONEY: You also said before the break 14 15 A. Yes. 15 that you generally catch diversion within a week; is that 16 MR. MOONEY: Let's take like a 15-minute break 16 right? 17 and I will... 17 A. That's right. 18 MR. ARBITBLIT: Thank you. 18 Q. How do you do that? 19 THE WITNESS: Thank you. 19 A. We have a very high level of scrutiny and 20 THE VIDEOGRAPHER: Going off the record, the 20 stewardship in our clinic, informed by my awareness of 21 time is 10:19 a.m. 21 this problem and my understanding of the disease of 22 22 addiction. So we dispense opioids on a weekly basis, and (Recess.) 23 THE VIDEOGRAPHER: Back on the record, the time 23 patients come in every week, and we check the 24 is 10:37 a.m. 24 prescription drug monitoring database in order to ensure Q. BY MR. MOONEY: Dr. Lembke, before the break, 25 25 that they're not going to other prescribers to get the Page 91 Page 93 1 you testified that a distributor has a responsibility to 1 same or similar prescription or engaging in dangerous 2 track what happens to the prescription after it's been 2 co-prescribing that we weren't previously aware of. We also get urine drug screens at every visit 3 dispensed, and in the case of finding a suspicious or 4 concerning situation, to intervene. 4 early in our opioid prescribing relationship and then at Was that your testimony? 5 random intervals later, in order to ensure that the 5 6 patient is taking the opioid that we are prescribing to 7 Q. How is a distributor supposed to track an 7 them and is not taking other substances that are 8 individual prescription? 8 prohibited through our patient-provider contract. A. There are other experts who will be testifying We have a patient-provider contract that we 10 on the legal responsibilities of distributors. That's 10 discuss what is -- what the patient's responsibilities 11 not my role here. But my opinion is that everybody in 11 are, what the provider's responsibilities are. 12 the opioid supply chain has a responsibility, and the 12 We also actively engage family members to gather 13 unique responsibility of distributors is to scrutinize 13 collateral information. We regularly check the 14 and identify suspicious orders or an area of the country 14 electronic medical record to see what other types of

17 Q. You also said, though, before the break that a

15 or a pharmacy where it appears that the supply of opioids

18 distributor has a responsibility to track what happens to

19 the prescription after it has been dispensed. My

20 question is: How do they do that?

16 is increasing beyond medical need.

A. I -- I can suggest ways that -- that they might

22 do that. I think that's maybe more appropriate for

23 abatement.

24 Again, the scope of my expert testimony is

25 really about the impact of increased supply on the rates

21 practice over time in recognition of the fact that 22 patients can at any point deviate from taking their

20 training. That's something that I have implemented in my

15 treatments or co-occurring medical problems the patient

So we have a very high level of scrutiny,

18 informed by regular monitoring, which, by the way, was

19 not the way that I was educated in medical school and

16 may have received or is receiving.

23 opioid as prescribed because of the overwhelming pull of 24 opioid medications and the vulnerability that we all have

25 to misuse or become addicted to these medications.

17

Page 94 Q. So the high level of scrutiny that you have

2 implemented in your practice, do you consider those to be

3 best practices?

1

- 4 A. I do, yeah.
- 5 Q. And are those best practices practices that are
- 6 followed in the State of New York?
- 7 MR. ARBITBLIT: Object to form.
- 8 THE WITNESS: I would say in general across the
- 9 country, including New York, that those have not been
- 10 standard practices, primarily because defendants created
- 11 a climate in which opioids were considered effective,
- 12 safe, and in which we were taught that the risk of
- 13 addiction through a doctor's prescription is very rare,
- 14 less than 1 percent.
- 15 And because of that, doctors came to believe and
- 16 were educated to believe that they have -- they could
- 17 have very low levels of scrutiny, as long as they were
- 18 prescribing for a patient with a legitimate pain
- 19 condition, as if that conferred some kind of immunity to
- 20 the problems related to opioids.
- A lot of my work is trying to implement the best
- 22 practices akin to what we do in our clinic and which
- 23 other clinics are doing now as well, as I alluded to
- 24 earlier in my conversation with the gynecologist in
- 25 Buffalo, New York. But it will take an infusion of
- Page 95
- 1 resources to provide the education and training and
- 2 medical infrastructure to implement best practices.
- 3 Q. BY MR. MOONEY: When you catch diversion, do you
- 4 alert authorities?
- 5 MR. ARBITBLIT: Object to form.
- 6 THE WITNESS: Our scrutiny is so close that when
- 7 I catch diversion in my patients -- and again, it's not
- 8 even that I have a certainty about diversion. Patients
- 9 will seldom, if ever, admit to diversion. But a way that
- 10 I might suspect division is, for example, I do a urine
- 11 drug screen and the urine drug screen does not detect the
- 12 opioid that I'm prescribing. And then I'm very worried
- 13 that the patient is diverting that opioid.
- Then I will have an informed discussion with
- 15 them, where I tell them about my concerns. Typically the
- $16\,$ patient will deny because that's the nature of the beast.
- 7 And then we will make modifications in the care
- 18 so that I can more closely steward that medication until
- 19 I have a level of certainty that the pill is not being 20 diverted.
- 21 If I can't obtain that level of certainty, then
- 22 I -- I don't prescribe that medication any longer. I try
- 23 to find some kind of alternative treatment.
- 24 Q. BY MR. MOONEY: When you confirm diversion, do
- 25 you alert legal authorities to that diversion?

- 1 MR. ARBITBLIT: Object to form.
- 2 THE WITNESS: I have not in my clinical
- 3 experience encountered diversion with such certainty that
- 4 I felt it was necessary to alert legal authorities. I've
- 5 had suspicion for diversion and have acted on those
- 6 suspicions.
- 7 Q. BY MR. MOONEY: So when you find something
- 8 suspicious but can't confirm that it's suspicious, your
- 9 practice is to not report that suspected diversion; is
- 10 that right?
- 11 A. That's right, because sometimes my suspicions
- 12 are unfounded. So, for example, the urine drug screen
- 13 has a certain sensitivity and specificity which is not
- 14 100 percent accurate or, you know, maybe the patient
- 15 missed their dose for a legitimate reason, which they
- 16 then explained to me.
- So a negative urine drug screen is evidence of
- 18 them not taking the medicine, but not because they're
- 19 diverting it, but because they forgot or they lost their
- 20 pills or what have you.
- So, you know, I have to gather as much evidence
- 22 as I can to make an informed clinical judgment, but as
- 23 soon as there's evidence of any kind of suspiciousness, I
- 24 act on that immediately. I discuss it with the patient,
- 25 I discuss it with their family members, I express the
 - Page 97

- 1 concern to my patient, and I change my prescribing.
- 2 MR. MOONEY: Move to strike everything after
- 3 "that's right."
- Q. Dr. Lembke, the question was: When you find
- 5 something suspicious but can't confirm that it's -- can't
- 6 confirm it's suspicious, your practice is to not report
- o commin it's suspicious, your practice is to not repor
- 7 that suspected diversion.
- 8 MR. ARBITBLIT: Object to form.
- 9 Q. BY MR. MOONEY: Is that right?
- 10 A. When I find something that's suspicious, my
- 11 practice is to report it to the patient, to report it to
- 12 concerned family members, to report it to my
- 13 interdisciplinary treatment team, to report it to the
- 14 dispensing pharmacist. That is my standard practice.
- I do not go to legal authorities because I have
- 16 never had occasion in which I was so convinced about
- 17 diversion that harmed -- that had the potential to harm a
- 18 large number of people, and I felt that I could contain 19 my -- what -- what -- what might be diversion within my
- 20 clinic by immediately changing my prescribing or my
- 21 intervention around that patient.
- Q. What threshold would you look for to be
- 23 convinced about diversion and harm that you would feel
- 24 the need to report it?
- MR. ARBITBLIT: Object to form.

Page 98 Page 100 1 THE WITNESS: It would depend on the 1 MR. ARBITBLIT: Object to form. 2 circumstances. These are judgment calls. But if I saw a 2 THE WITNESS: I'm not sure about the nuances of 3 consistent repeated pattern of pills that I was 3 New York State's rules and regulations regarding 4 prescribing not being taken by my patient and ending up 4 licensure and prescribing privileges. If it's similar to 5 with somebody else, I would report it. 5 other states, then the Board is involved in licensure as Q. BY MR. MOONEY: You never called the police to 6 well as specifically the DEA is involved in granting 7 report diversion from your patients? 7 permission to prescribe controlled substances. Q. BY MR. MOONEY: Does the New York Board of 8 A. I am remembering a situation in which I was 9 Medicine have the power to investigate doctors? 9 discussing with police a case of diversion, but I don't 10 remember if I initiated the call or if somebody else did. 10 A. Yes. Q. Have you ever called the DEA to report diversion 11 Q. Can it discipline doctors? 12 from your patients? 12 13 A. No. 13 Q. Can the Board of Medicine take away a doctor's Q. Who is the last patient of yours who you had 14 14 license? 15 suspicions was diverting opioids? 15 A. Yes. MR. ARBITBLIT: Object to form and invades 16 16 Q. If a doctor losses their medical license, can 17 confidentiality. 17 they prescribe opioids? A. No. 18 THE WITNESS: Yeah, I can't talk about a 18 19 specific patient scenario. 19 Q. They can't practice medicine at all in that 20 Q. BY MR. MOONEY: What condition did the patient 20 state; right? 21 have? 21 A. That's right. 22 Q. Are you familiar with the Federation of State 22. A. The patient had opioid use disorder, opioid 23 addiction. 23 Medical Boards? 24 24 A. Yes. Q. And was that patient with opioid use disorder 25 being prescribed opioids? 25 Q. What is the Federation of State Medical Boards? Page 99 Page 101 A. Yes. A. The Federation of State Medical Boards is the 1 1 2 Q. Does every state have a medical board? 2 umbrella organization for the individual State Medical 3 A. To my knowledge, yes. O. And is the New York State Medical Board a member 4 Q. What's the New York medical board called? 4 A. New York State Medical Board. 5 of the Federation of State Medical Boards? Q. That's what it's called? A. I assume so. 7 A. I believe so, yes. 7 Q. Are medical boards from all 50 states members of 8 the Federation? Q. Is it true that doctors who -- or excuse me, 9 does the New York -- strike that. My microphone fell. A. I assume so, but I don't know for sure. 10 Does the New York Board of Medicine license 10 Q. Is CardinalHealth, McKesson, AmerisourceBergen 11 doctors? 11 or Rochester Drug Co-op a member of the Federation of 12 A. Yes, I believe so. I believe they're a 12 State Medical Boards? 13 licensing body as well as a monitoring organization. 13 A. I don't believe so. Q. Does the State of New York also license doctors Q. As part of its work overseeing State Medical 15 who describe pain medications to prescribe those 15 Boards, did the Federation release model guidelines for 16 medications? 16 prescribing opioids? 17 MR. ARBITBLIT: Object to form. 17 A. Yes, they did. THE WITNESS: There are multiple different Q. And when did the Federation first issue those 18 19 organizations involved in physician licensure. So the 19 guidelines? 20 State Board is -- is one of those, but when it comes 20 A. I do reference that in my report. 21 specifically to prescribing, the DEA is also involved. 21 MR. MOONEY: You can take the time to look, but O. BY MR. MOONEY: So there's Board of Medicine 22 you might look at page 26. 23 23 licensing and the DEA. Does the State of New York also THE WITNESS: Thank you. I appreciate it. 24 license prescribers to engage in controlled substance 24 So the Federation of State Medical Boards 25 activity? 25 published the book -- published a book. In 1998, the

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- 1 Federation of State Medical Boards released a policy to
- 2 reassure doctors that they would not be prosecuted if
- 3 they prescribed even large amounts of opioids. And then
- 4 they released a book in 2007 called "Responsible Opioid
- 5 Prescribing, a Physician's Guide."
- Q. BY MR. MOONEY: Okay.
- 7 A. Does that answer your question?
- 8 Q. Sort of.
- Did the DEA endorse the Federation's model
- 10 guidelines?
- 11 A. I don't believe the DEA was involved in
- 12 endorsing the model guidelines.
- Q. Do you know if the DEA testified in support of
- 14 the Federation's model guidelines?
- 15 A. If they did, I'm -- I'm not aware of that.
- Q. As part of the Federation's policy, did the
- 17 model guidelines reassure doctors that they would not be
- 18 prosecuted if they prescribed large amounts of opioids
- 19 for the treatment of pain?
- A. It is certainly true that through the
- 21 campaigning of the Pain and Policy Study Group from
- 22 Wisconsin, Drs. David Joranson and June Dahl, promoted by 22 Responsible Opioid Prescribing, they distributed copies
- 23 the American Pain Society and funded indirectly by the
- 24 opioid manufacturers, that there was a lobbying campaign
- 25 during which Drs. Joranson and Dahl went to different
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- 1 state federation -- different State Medical Boards
- 2 encouraging them to pass laws and guidelines stating that
- 3 doctors who prescribed very high amounts of opioids would
- 4 not be -- would not be punished in any way, as long as
- 5 they were prescribing those opioids for the treatment of
- 6 pain.
- 7 Q. So --
- 8 A. Yes. The answer to your question is "yes."
- Q. Right. In romanette II you say: "In 1998, the
- 10 Federation of State Medical Boards released a policy to
- 11 reassure doctors that they would not be prosecuted if
- 12 they prescribed even large amounts of opioids as long as
- 13 it was for the treatment of pain."
- Did I read that correctly?
- 15 A. Yes.
- 16 Q. And that is an opinion that you hold?
- 17 A. That's correct.
- 18 Q. Did the Federation urge the State Medical Boards
- 19 to punish doctors for under-treating pain?
- 20 A. Yes, they did.
- Q. Has the New York Board of Medicine ever punished
- 22 doctors for under-treating pain?
- 23 A. I'm not aware of specific cases.
- 24 Q. Are doctors afraid of being disciplined by their
- 25 State Medical Board and facing lawsuits if they don't

- 1 prescribe opioids for their patients to address pain?
- A. That was true in the late 1990s and early aughts
- 3 through about 2012 or 2013. I think that's less true
- 4 now
- 5 Q. Did the New York Board of Medicine implement the
- 6 Federation's model guidelines?
- 7 A. I don't know.
- 8 Q. Now, you mentioned a couple moments ago that the
- 9 Federation also published a book that promoted the use of
- 10 prescription opioids; is that right?
- 11 A. That's right.
- 12 O. And what was the title of that book?
- 13 A. Responsible Opioid Prescribing, a Physician's
- 14 Guide.
- 15 Q. And when was that book released?
- 16 A. 2007.
- 17 Q. Did CardinalHealth, McKesson, AmerisourceBergen
- 18 or Rochester Drug Co-op provide any funding for that
- 20 A. Not that I'm aware of.
- 21 Q. The Federation didn't just publish the book
- 23 to State Medical Boards; is that right?
- 24 A. That's right.
- 25 Q. And then the State Medical Boards distributed

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- 1 that book to its licensees?
- A. I don't know whether they distributed it for
- 3 free or if it was available for purchase, but it was
- 4 certainly available to their licensees.
- O. So just so I make sure I understand, the
- 6 Federation of State Medical Boards of all of the State
- 7 Medical Boards published a treatment guideline and
- 8 published a book telling doctors that it's generally
- 9 accepted medical practice to prescribe the opioids as a
- 10 first-line treatment for chronic pain.
- 11 Is that accurate?
- 12 A. So I have read the book Responsible Opioid
- 13 Prescribing, and I would say that it contains within it
- 14 many of the misleading promotional messages that I've
- 15 detailed here in my report, for example, that opioids are
- 16 an evidence-based treatment for chronic pain. That is a
- 17 misleading message. That the risk is low or that no dose 18 is too high, et cetera.
- 19 There is some good information in that book.
- 20 It's not all bad information. But there's certainly
- 21 enough bad information in that book to make it suspect.
- 22 Q. Okay. So just focusing in on the question: The
- 23 Federation of the State Medical Boards published
- 24 treatment guidelines and published a book telling doctors
- 25 that it's generally accepted medical practice to

Page 106 1 prescribe opioids for chronic pain; is that right?

- 2 A. That's right.
- Q. And is it your opinion that these guidelines
- 4 made the opioid epidemic worse?
- A. They contributed, yes.
- 6 Q. And is that because the guidelines largely did
- 7 away with the restrictions that had previously existed on
- 8 how opioids were prescribed?
- 9 A. It's a combination of doing away with the
- 10 Federation of State Medical Boards' level of scrutiny on
- 11 how doctors were prescribing opioids, condoning high
- 12 volume prescribing and high-dose prescribing.
- But I think even more importantly, that book was
- 14 one of many pieces that really changed the culture around
- 15 opioid prescribing, such that prescribing very high doses
- 16 and very large volumes, even for minor and chronic pain
- 17 conditions, became normative in medicine.
- 18 Q. Is the New York Medical Board still a member of
- 19 the Federation of State Medical Boards?
- A. I don't know. I assume so, but I don't know.
- 21 Q. Do you know if the New York Attorney General has
- 22 sued the Federation of State Medical Boards for
- 23 publishing guidelines that contributed to the opioid
- 24 epidemic?
- A. I'm not aware of that.

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- 1 certain quality measures and how to meet those quality
- 2 measures, and hospitals and clinics who meet those
- 3 measures can be accredited by the Joint Commission and
- 4 get a kind of seal of approval, which is very important,
- 5 has been historically very important for healthcare
- 6 institutions.
- 7 And that seal of approval not only is a public
- 8 statement to the quality of their care, but again, also
- 9 makes them eligible for certain types of reimbursement.
- 10 Q. And so does meeting those quality measures
- 11 depend on following the best practices that are
- 12 determined by the Joint Commission?
- 3 A. Yes, meeting those quality measures is dependent
- 14 on following best practices determined by -- as
- 15 determined by the Joint Commission and as measured in the
- 16 way that the Joint Commission says they need to be
- 17 measured.
- 18 O. And has the Joint Commission introduced
- 19 standards for the treatment of pain?
- 20 A. Yes. In 2001, the Joint Commission made pain a
- 21 quality measure and implicitly suggested the ways in
- 22 which hospitals and clinics should implement that quality
- 23 measure.
- Q. And did the Joint Commission's quality measures
- 25 promote more liberal prescribing of opioids for pain?

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- Q. Have you publicly condemned your colleagues on
- 2 State Medical Boards for promoting the model guidelines?
- 3 A. Yes.

1

- 4 O. Where?
- 5 A. I've given talks, and in my book, I talk about
- 6 the role of the Federation of State Medical Boards. I
- 7 wouldn't say I've publicly condemned certain individual
- 8 colleagues, but as one brick, you know, in a larger, you
- 9 know, wall of this problem, the Federation of State
- 10 Medical Boards has played a role in contributing to the
- 11 opioid epidemic in the ways that I have just said and
- 12 also in the ways that I detail in my report.
- 13 Q. Are you familiar with the Joint Commission on
- 14 Accreditation of Healthcare Organizations?
- 15 A. Yes, I am.
- 16 Q. It's often referred to as the Joint Commission?
- 17 A. Yes.
- 18 Q. What is the Joint Commission?
- 19 A. The Joint Commission is a non-profit
- 20 organization that was designed to accredit hospitals to
- 21 ensure that patients are receiving a high level of care.
- 22 And hospitals and clinics are eager to get Joint
- 24 eligible for funds from Medicare and Medicaid.
- 25 So what the Joint Commission does is establish

23 Commission accreditation in order to, for example, be

- Page 109

 A. Yes. It was a combination not only of making
- 2 pain a quality measure, but also dispensing to hospitals
- 3 for a fee educational materials obtained from opioid
- 4 manufacturers on how that could be done. And those --
- 5 those quote/unquote learning materials contained much of
- 6 the misinformation propagated by defendants that led to
- 7 this opioid epidemic, things like doctors who don't
- 8 prescribe opioids for pain are suffering from
- 9 quote/unquote opioid phobia and implied irrational fear 10 of opioids.
- 11 The idea that every pain patient can be assessed
- 12 using the pain scale from 1 to 10, and that should be
- 13 assessed using that pain scale, whether or not they
- 14 appear to have any kind of pain.
- 15 The misrepresentation of the risk of opioids,
- 16 including that patients -- that it's very rare for
- 17 patients to get addicted to opioids as long as they're
- 18 being prescribed by a doctor, when, in fact, there is
- 19 good evidence that predates this epidemic and has been
- 20 validated in ongoing research that the risk is actually
- 21 very common among patients treated for pain. That's all
- 22 in my report.
- 23 MR. MOONEY: Move to strike everything after
- 24 "yes."
- 25 Q. My question was: Did the Joint Commission's

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1 quality measures promote more liberal prescribing of

- 2 opioids for pain?
- 3 A. Yes.
- 4 Q. And is it a practical effect of those standards
- 5 that hospitals had to follow them or risk losing
- 6 accreditation?
- 7 A. Yes, I believe that's true.
- 8 Q. Are you familiar with the concept of a vital 9 sign?
-) 51**511.**
- 10 A. Yes, I am.
- 11 Q. What is a vital sign?
- 12 A. A vital sign is an objective measure of a
- 13 patient's health, including heart rate, breathing rate,
- 14 blood pressure and temperature. Those four have been the
- 15 classic and enduring vital signs in medicine for decades.
- 16 The Joint Commission advocated pain measure and
- 17 the 1 to 10 pain scale as another way to -- as a way that
- 18 doctors should measure pain, and that pain should be like
- 19 the fifth vital sign. That was the terminology. I don't
- 20 think the Joint Commission invented that, but in their
- 21 collaboration with the American Pain Society and key
- 22 opinion leaders, came up with the idea of pain as the
- 22 opinion leaders, came up with the idea of pain as the
- 23 fifth vital sign, and the Commission adopted and
- 24 disseminated that idea in order to meet their quality
- 25 measure. So yes.

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- 1 Q. And what is the significance of treating pain as 2 a vital sign?
- A. The significance of treating pain as a vital
- 4 sign is that any patient who walks through your office or
- 5 clinic or emergency room or hospital door for any reason
- 6 should have their pain assessed along with their blood
- 7 pressure, heart rate, temperature, et cetera, just as the
- 8 standard of care.
- 9 Unfortunately, there's no evidence to support
- 10 the use of the visual analog scale, or the 1 to 10 pain
- 11 scale, in terms of pain outcomes. And in fact, data show
- 12 that asking patients to rate their pain on a scale from 1
- 13 to 10 just leads to more opioid prescribing and doesn't
- 13 to 10 just leads to more opioid prescribing and doesn
- 14 improve pain outcomes.
- 15 Q. So did treating pain as a vital sign encourage 16 prescribing more opioids for pain?
- 17 A. Yes.
- 18 Q. Do patient satisfaction surveys influence
- 19 doctors to prescribe opioids more liberally?
- 20 A. Yes.
- Q. How do they do that?
- A. As I talk about in my report and also in my
- 23 book, doctors are kind of natural pleasers and natural
- 24 helpers, and they are very compassionate people, by and
- 25 large, and they want to help their patients. And they're

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- 1 also eager to have their patients like them. And so that
- 2 can make that dynamic between doctor and patient and
- 3 opioid prescribing very complicated.
- 4 Because opioids can be effective for pain in the
- 5 short-term, when doctors prescribe them, patients do
- 6 endorse significant, immediate relief, and that feels
- 7 really good for doctors.
- 8 And then that's -- the complexity there is added
- 9 to by the fact that many hospitals ask their patients to
- 10 rate their doctors on, you know, on how good they are, as
- 11 well as there are national surveys asking patients to
- 12 rate the hospital, did your hospital or your clinic do
- 13 everything in their power to address your pain.
- 14 And then those ratings are communicated back to
- 15 doctors, and if they're not good ratings, then doctors
- 16 really are called to task on why their patients are not
- 17 rating them highly, which can contribute to opioid
- 18 overprescribing.
- 19 Q. Have you quantified the impact that patient
- 20 satisfaction surveys have on doctors' decisions to
- 21 prescribe opioids?
- A. What do you mean by "quantify"?
- 23 Q. Well, have you -- can you provide a percentage
- 24 of a doctor's decision making for which patient
- 25 satisfaction surveys played a role in prescribing

- 1 opioids?
 - A. I can't quantify it numerically, but based on my
- 3 personal experience, my clinical experience, and also my
- 4 many conversations with doctors, patient satisfaction
- 5 surveys have played a big role.
- 6 Q. Are you aware that the DEA sets a quota on the
- 7 number of prescription opioids that can be manufactured
- 8 in a given year?
- 9 A. Yes.
- 10 Q. Do you agree that the DEA's quota impacts the
- 11 supply of opioids that are available?
- 12 A. I really think it's out of my area to opine on
- 13 that. There will be other experts who will speak to
- 14 specific quotas and the legal obligations of
- 15 manufacturers vis-à-vis quotas. That's not -- not really
- 16 my area.
- 17 Q. My question wasn't about the manufacturer's role
- 18 in the quota. My question was just do you believe. I
- 19 understand there may be other experts who are going to 20 opine on this.
- 21 My question: Do you agree that the DEA quota
- 22 has an impact on the supply of prescription opioids that
- 23 are available in the market?
- 24 MR. ARBITBLIT: Object to form.
- 25 THE WITNESS: Yes. That makes sense.

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- 1 Q. BY MR. MOONEY: Should the DEA's quota be lower?
- 2 A. I don't feel that I really know enough about the
- 3 impact of quotas to be able to offer an opinion on that.
- 4 Q. On page 58 of your report, you write that the
- 5 best evidence available shows that the risk of addiction
- 6 in patients taking opioids for chronic pain is between
- 7 10 percent and 30 percent.
- 8 Do you see that?
- 9 A. Yes.
- 10 Q. Assuming that those percentages are accurate,
- 11 what is the appropriate number of prescription opioids
- 12 that a distributor should ship to a pharmacy?
- 13 MR. ARBITBLIT: Object to form.
- 14 THE WITNESS: That's really outside -- those
- 15 calculations are outside of my expertise.
- 16 Q. BY MR. MOONEY: What percentage of Americans
- 17 have ever taken a prescription opioid as prescribed by a
- 18 doctor?
- 19 A. So I do talk about that a little bit in my
- 20 report. Let me refer to that section.
- 21 So in 2016, I coauthored an article on the use
- 22 of opioid agonist therapy in the treatment of opioid use
- 23 disorder, but as part of the quantitative analysis that
- 24 we did for this publication, we also assessed the
- 25 percentage of Medicare Part D enrollees who fill at least

1 pharmaceutical opioid industry and in the medical

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- 2 profession and representatives in Public Health and
- 3 across the nation, to try to zero in on what that lower
- 4 number should be.
- 5 Q. BY MR. MOONEY: Do you know if any of the
- 6 10 million Part D Medicare enrollees in your report had
- 7 their claims rejected?
- A. I don't know. We did not analyze that.
- 9 Q. Do you agree that heroin and fentanyl use in the
- 10 United States has increased over the past five years?
- 11 A. Yes.
- 12 Q. Is nonmedical prescription opioid use a
- 13 significant factor that contributed to the increase in
- 14 heroin and fentanyl use?
- 15 MR. ARBITBLIT: Object to form.
- 16 THE WITNESS: Both medical and nonmedical use
- 17 have contributed to the use in heroin and illicit
- 18 fentanyl use.
- 19 Q. BY MR. MOONEY: What is "nonmedical prescription
- 20 opioid use"?
- 21 A. Nonmedical opioid use means taking an opioid in
- 22 any way other than indicated by the doctor and by the
- 23 prescription.
- 24 Q. Between medical and nonmedical prescription
- 25 opioid use, which one of those two has played a larger

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- 1 one opioid prescription in any given year, and we
- 2 calculated that more than 10 million Part D Medicare
- 3 enrollees are exposed to a prescription opioid in any
- 4 given year.
- 5 And the Medicare Part D sample is a good sample
- 6 because Medicare Part D recipients can be found across
- 7 the country. So it's a very representative sample of the
- 8 US population.
- 9 And although I know that doesn't specifically
- 10 answer your question of what percentage of Americans have
- 11 ever taken a prescription opioid, it's a very large
- 12 number of individuals who have been prescribed an opioid.
- 13 I can't give you an exact percentage.
- 14 And this -- this data point conveys or
- 15 illustrates that we're talking about tens of millions of
- 16 Americans.
- 17 Q. And in your opinion, is that tens of millions of
- 18 Americans number too high?
- 19 A. Yes.
- Q. What should the number be?
- 21 MR. ARBITBLIT: Object to form.
- THE WITNESS: It's hard for me to say at this
- 23 juncture what that number should be. I think it should 24 be lower. Exactly how much lower, I'm not sure, but I
- 25 think it is our responsibility both, you know, in the

- ge 113
 - 1 contribution in heroin and fentanyl use?
 - 2 MR. ARBITBLIT: Object to form.
 - 3 THE WITNESS: Both have played a very
 - 4 significant role. Legitimate prescription opioid use can
 - 5 lead a patient to engage in nonmedical prescription
 - 6 opioid use, which increases their risk 40-fold then of
 - 7 progressing to heroin use, for the Compton 2016 article.
 - 8 There's also good evidence via the McCabe 2017
 - 9 reference in my report that medical use of prescription
 - 10 opioids actually precedes nonmedical use, and that
 - 11 nonmedical use followed by medical use in the McCabe 2019
 - 12 article exacerbates the development of a substance use
 - 13 disorder.
 - 14 There's also the scenario in which people in the
 - 15 last three decades, growing numbers have engaged in
 - 16 nonmedical use because of diversion. People who got
 - 17 pills from a drug dealer or from a friend at school or
 - 18 from grandma's medicine cabinet. People who did not
 - 19 interface at all with the medical community, which really
 - 20 speaks to the oversupply of opioids broadly in our
 - 21 society being a major factor in this epidemic.
 - Q. The Muhuri report, though, said that 70 percent
 - 23 of misusers used illegal drugs before they used opioids;
 - 24 isn't that right?
 - 25 A. Go to that.

30 (Pages 114 - 117)

Page 118 Page 120 1 So as I state in my report, in a study based on 1 2013, marked for identification.) 2 the National Survey of Drug Use and Health Data -- this 2 THE WITNESS: Do you have a page that you quoted 3 is page 96 of my report -- from 2002 to 2011, the 3 from? 4 incidence of heroin use among people who reported prior 4 O. BY MR. MOONEY: Yes. 5 nonmedical use of prescription opioids was 19 times as 5 First, can you identify what's been marked as 6 high as the incidence among persons who reported no 6 Exhibit 4 to your deposition? 7 previous nonmedical use. A. Yes. This is Muhuri, "Associations of 8 Nonmedical Pain Reliever Use and Initiation of Heroin Use So that's an important data point to show the 9 clear association between nonmedical use of prescription 9 in the United States." 10 opioids and heroin use. But this is also an incidence 10 Q. Now if you would turn to the page that ends at 11 the bottom in 6042, Table 6. 11 study so it doesn't capture the full prevalence of 12 individuals who -- in the population who have an opioid 12 A. Uh-huh. 13 use disorder or use heroin. 13 Q. Just before we talk about that page, I just want 14 14 to clarify. This Exhibit 4 is the report that you cite So it's an important data point to show the 15 in footnote 410 of your report? 15 association between nonmedical use and heroin use, but 16 there's also a very strong association between medical 16 A. Yes. 17 use and nonmedical use and then the progression to heroin 17 Q. Okay. So Table 6 lays out the percentage 18 use. 18 distribution of past-year nonmedical pain reliever use 19 If you look at page 86 of my report, McCabe 19 among persons age 12 to 49 at risk for initiation of 20 2017. McCabe writes that: "We found that the majority 20 nonmedical pain reliever use by prior drug use status. 21 of nonmedical users of prescription opioids involved a 21 Is that right? 22 history of medical use, and this finding should provide 22 A. Uh-huh, uh-huh. 23 some concern to health professionals who prescribe opioid 23 Q. And under the "no heroin use prior to NMPR use, 24 medications to adolescents, given the serious health 24 is "NMPR" --25 consequences associated with nonmedical use of 25 A. Uh-huh. Page 119 Page 121 1 prescription opioids." Q. -- nonmedical pain reliever use? 1 2 2 So there is a very clear stepping-stone effect A. Uh-huh. 3 Q. It says: "Other illicit drug use" -- "drugs 3 from medical use to nonmedical use to heroin use. That's 4 not the only pathway. There's also a pathway that begins 4 used prior to NMPR use." 5 with nonmedical use, and that's become increasingly more 5 Do you see that? 6 prevalent because of the increased supply, and that then A. Uh-huh. 7 leads to heroin use. Q. If you go to the right, under the column 2002 to So there's -- those -- those things are closely 8 2011, it says 71.8 percent; is that right? 8 9 intertwined. 9 A. Uh-huh. 10 10 I would also say that these pieces of evidence Q. And so does this table say that 71.8 of persons 11 from the peer-reviewed literature support my clinical 11 who did not use heroin before using nonmedical pain 12 experience, in which I have had countless patients report 12 relievers -- or excuse me -- using pain relievers for 13 nonmedical use, were using other illicit drugs before 13 to me that their opioid addiction began with a 14 prescription from a well-intended healthcare provider for 14 eliciting nonmedical pain reliever use? 15 15 the treatment of pain. A. Yes, it does say that. Q. The Muhuri 2013 report found that more than 16 Q. And then footnote 2, which follows other illicit 17 drugs, reads: "Other illicit drugs include marijuana, 17 70 percent of heroin users started with illicit drugs 18 hashish, cocaine, including crack, hallucinogens and 18 prior to their nonmedical prescription use; is that 19 right? 19 inhalants." 20 20 MR. ARBITBLIT: Object to form. Did I read that right? THE WITNESS: Could I see? I don't have the 21 22 article right in front of me. I believe you, but it 22 Q. Of all the people -- you can set that aside. 23 would be nice to look at the actual article. 23 Of all the people who get an opioid prescription 24 MR. MOONEY: Mark this as 4, I think. 24 from their doctor, how many go on to use heroin or

25 fentanyl?

(Exhibit 4, CBHSQ Date Review, SAMHSA, August

25

Page 122 Page 124 1 A. Well, that's a different question. 1 fentanyl; is that correct? 2 2 Q. It is. MR. ARBITBLIT: Object to form. 3 A. That's based -- yeah. So I think you've asked 3 THE WITNESS: Well, I did prescribe a number 4 that before. The most reliable version of that -- let me 4 that I think is very evidence based and reliable on what 5 try to answer, again, we're better. 5 percentage of patients prescribed an opioid by their So the most reliable data show that 6 doctor for a legitimate pain condition will go on to 7 approximately 10 to 30 percent of patients treated with 7 develop an opioid addiction, somewhere between 10 and 8 an opioid for pain have some kind of opioid use disorder, 8 30 percent, which is very common. 9 and it's the natural history of the disease of addiction And then if we extrapolate from that that we've 10 that patients will over time need more and more of that 10 got tens of millions of Americans, you know, who are 11 opioid to get the same effect and that they will look for 11 exposed to opioids, you know, you could come up with a 12 cheaper and more readily available sources. 12 number for that. 13 So when -- once people are addicted through a Q. BY MR. MOONEY: Can you come up with a number 13 14 prescription opioid, it is not uncommon for them to then 14 for that sitting here today? 15 progress to heroin, and we do know that our heroin supply 15 A. I'd rather not give a specific number. I think 16 has been adulterated by illicit fentanyl. 16 the evidence is in my report and based on percentages. 17 And so, you know, I don't have data exactly on 17 Q. So the answer is "no," today, sitting here, you 18 how many of those patients addicted through a 18 can't give a number? 19 prescription progressed to heroin, but the odds ratios 19 A. Yes, that's right. 20 from Compton 2016 show that they are 40 times more likely 20 Q. On page 85 of your report in paragraph D, you 21 to progress to heroin use having been exposed to a 21 write: "It is important to recognize that although many 22 prescription opioid. 22 of the communities hit hardest by the opioid epidemic 23 And again, the McCabe and my own experience 23 were already struggling with serious social and economic 24 suggests that a very large proportion of individuals who 24 problems, the sudden availability of easy access to 25 have become addicted to heroin in the last 20 to 30 years 25 opioids, initially in prescription pill form, contributed Page 123 Page 125 1 started out with a prevention opioid. 1 to the economic and social devastation of many towns 2 There's also an article that I reference here 2 across America." 3 based on a survey study showing that three-quarters of 3 Did I read that correctly? 4 heroin users say that their first exposure to opioids was 4 A. Yes. 5 a prescription opioid. And that's page 96, Cicero, JAMA 5 Q. You're not an economist, are you? 6 Psychiatry 2014. 7 And I'll just read from that. "In the 1960s, Q. Are you a sociologist? 8 80 percent of opioid users reported that their first 8 A. Armchair sociologist? 9 exposure to opioids was in the form of heroin. By the 9 Q. Trained -- trained sociologist? 10 10 2000s, however, 75 percent of opioid users reported that A. I don't have any degrees in sociology, per se. 11 their first exposure to opioids was in the form of 11 Q. Have you done any independent analysis of 12 prescription painkillers," really demonstrating a massive 12 economic and social devastation across many towns in 13 paradigm shift in terms of the heroin users in this 13 America? 14 country today compared to the 1960s. 14 15 15 MR. MOONEY: Move to strike all of that. Q. Have you done any independent analysis of the Q. Dr. Lembke, my question was: How many people 16 causes of any economic and social devastation across many 17 towns in America? 17 who get opioid prescriptions from their doctor end up 18 18 going on to use heroin or fentanyl? A. No. 19 MR. ARBITBLIT: Object to form. 19 Q. Do you have any other opinions about 20 THE WITNESS: I couldn't give you an absolute 20 distributors that are not listed in your report, that you 21 number. I've tried to suggest an answer through 21 intend to offer in this litigation? 22 percentages. 22 A. My opinions in the report as well as in my 23 Q. BY MR. MOONEY: So sitting here today, you 23 testimony today are the opinions I intend to offer in 24 cannot provide a number of how many people who are 24 this litigation. 25 25 prescribed opioids by their doctor end up using heroin or Q. When we started this deposition, I handed you

Page 126 Page 128 1 what was marked as Exhibit 1. 1 A. No. 2 Do you remember that? 2 Q. Are you aware of any pharmacy presenter at the 3 A. Yes. 3 2001 CME that you attended? O. And you said Exhibit 1 was a -- or excuse me, 4 A. Not that I recall. 5 Exhibit 2. I meant to say Exhibit 2. I handed you Q. And am I correct in your report for this case, 6 you have not identified any marketing statements by 6 Exhibit 2. 7 A. Yes. 7 retail pharmacy defendants; correct? A. That's correct. 8 Q. And that was your report from your -- from this 9 case; is that right? Q. In preparing your report for this case, did you 10 A. Yes, that's correct. 10 consider any documents produced from the files of a 11 Q. And you have not referred to that report in the 11 pharmacy defendant? 12 course of answering your -- answering my questions during 12 A. No. 13 today's deposition, that physical copy that is marked as 13 Q. Have you reviewed the testimony of any employees 14 Exhibit 2; right? 14 or witnesses from a pharmacy defendant in connection with 15 A. That's correct. 15 your work in this case? Q. You came in with a binder today that includes 16 16 A. No. 17 Post-It notes and notations? 17 Q. Earlier today you had some comments regarding 18 A. Yes. 18 the responsibility of pharmacists. I want to follow up 19 MR. MOONEY: I would like to mark that document 19 on that, okay? 20 You mentioned that pharmacies also have a 20 as Exhibit 5 to this deposition. 21 MR. ARBITBLIT: No objection. 21 responsibility in the opioid supply chain to make sure 22 22 that a patient customers are not being harmed by the (Exhibit 5, Dr. Lembke binder, notes and 23 23 opioids that are dispensed. notations, marked for identification.) 24 MR. MOONEY: We can take a break. 24 Do you recall saying that? MR. ARBITBLIT: Are you releasing the witness or 25 25 A. Yes, I do. Page 127 Page 129 Q. Okay. Is that opinion reflected anywhere in 1 not? You're just going to go think about it? 1 2 MR. MOONEY: We've got to go see what that 2 your report for this case? 3 document is. A. It's reflected broadly in my opinion that the 4 4 oversupply of opioids to Americans has been a major MR. ARBITBLIT: Fair enough. 5 contributor to this epidemic of addiction and overdose THE VIDEOGRAPHER: Going off the record, the 5 6 time is 11:27 a.m. 7 Q. Does that specific claim or opinion, is that (Lunch recess.) 8 noted anywhere in your report, the one that I just read 8 THE VIDEOGRAPHER: Back on the record. The time 9 to you? 9 is 12:16 p.m. 10 A. I don't specify a pharmacy in my report. 10 MR. MOONEY: Dr. Lembke, I have no further 11 11 questions. Thank you for your time. Q. And in your report, you do not mention any THE WITNESS: You're very welcome. 12 pharmacy by name; correct? 12 13 **EXAMINATION** 13 A. That is correct. 14 Q. BY MR. CARTER: Good afternoon, Dr. Lembke. 14 Q. With respect to the statement you made this 15 A. Good afternoon. 15 morning regarding pharmacy responsibility to make sure Q. My name is Ed Carter. We have not met before, 16 that patients are not being harmed by the opioids that 17 but I represent Walmart, and I have some questions to you 17 are dispensed, do you have any opinion in this case that 18 any of the pharmacy defendants did not comply with that 18 today, okay? 19 responsibility you articulated? 19 A. Yes. 20 Q. Can you identify any false or misleading claim 20 A. I am aware based on reports in the lay press and 21 about opioids made by one of the retail pharmacy 21 in other non-confidential documents and readings that I 22 have done that there are rogue pharmacies out there 22 defendants in this case? 23 23 dispensing very large quantities of opioids, far more 24 opioids than can be justified by the need for analgesia 24 Q. Are you aware of any marketing of opioids 25 in that community, and I don't know if any of those are 25 conducted by any of the retail chain pharmacy defendants?

Page 130 1 either -- are Walgreens or Walmart.

- Q. Okay. Do you know who the pharmacy defendants
- 3 are in the case brought by Nassau County?
- 4 A. I believe Walgreens and Walmart are the pharmacy
- 5 defendants in the case brought by Nassau County. CVS may
- 6 also be included, but I'm not sure.
- 7 Q. All right. Any other defendants that you're
- 8 aware of as defendants in the Nassau County case?
- 9 A. No.
- 10 Q. Do you know who the pharmacy defendants are in
- 11 the Suffolk County case?
- 12 A. I believe it's the same pharmacies.
- 13 Q. Okay. Any evidence that Walgreens, Walmart or
- 14 CVS in Nassau County failed to comply with the
- 15 responsibility to ensure that their patients, customers,
- 16 were not being harmed by the opioids that they dispensed?
- 17 A. I don't have knowledge of the specific
- 18 pharmacies in those counties.
- 19 Q. Fair to say you have not conducted any
- 20 systematic analysis or review of pharmacy dispensing data
- 21 in Nassau County?
- 22 A. Let me look at my report. I have reviewed data
- 23 on page 17 as pertains to the morphine milligram
- 24 equivalents dispensed in the state of New York, including
- 25 Nassau and Suffolk Counties, as well as the duration of

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- 1 prescriptions, namely, that in the state of New York,
- 2 opioid prescribing increased from 101 morphine milligram
- 3 equivalents in 1997 to 442 morphine milligram equivalents
- 4 by 2006, and again increased to 492 morphine milligram
- 5 equivalents per person in 2016, and this correlates with
- 6 the four-fold increase in opioid-related deaths in the
- 7 state of New York in that time period.
- 8 Also, the length of opioid prescriptions
- 9 increased during that time, going from 15 days in 2006 to
- 10 19 days of opioids in 2017.
- I also have CDC data looking at the opioid
- 12 prescribing rates specifically in Nassau County, which
- 13 increased from 47 opioid prescriptions per 100 persons to
- 14 51 opioid prescriptions per 100 persons from 2006 to
- 15 2011.
- 16 And in Suffolk County, I reviewed data showing
- 17 that opioid prescriptions increased from 61 opioids per
- 18 100 persons to 70 prescriptions per 100 persons in 2011.
- 19 Those are data that I reviewed specifically
- 20 regarding opioid prescribing in Nassau and Suffolk County
- 21 and New York, in the state of New York.
- Q. Do you know, are any of those data sources
- 23 pharmacy dispensing data sources?
- 24 A. I believe that the CDC data, the number of
- 25 opioid prescriptions per 100 persons is based on

1 pharmacy dispensing data.

- Q. Have you heard of ISOP?
- 3 A. What does "ISOP" stand for?
- 4 Q. I'm asking you. Have you heard of that acronym?
- 5 A. Oh. I don't know the acronym. I might know if
- 6 you tell me what it stands for. It might ring a bell.
- 7 Q. Have you reviewed the State of New York's PMP
- 8 drug data?
- A. Is that the prescription drug monitoring
- 10 database in the State of New York?
- 11 O. Yes.
- 12 A. No, I have not.
- Q. And with respect to any specific pharmacy in
- 14 Nassau or Suffolk, have you analyzed their dispensing
- 15 history to determine whether that pharmacy has adequately
- 16 attended to the safety of their customers?
- 17 A. No, I have not.
- 18 Q. You also discussed earlier today the following
- 19 statement. You said that pharmacists have a
- 20 responsibility to patients to ensure that the
- 21 prescription is appropriate, that it is a true
- 22 prescription, and that it is not a prescription that will
- 23 harm the patient.
- 24 Do you recall giving that testimony?
- 25 A. Yes, I do.

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- 1 Q. Okay. Is that -- are any of those statements
- 2 contained expressly in your report for this case?
- 3 A. Not expressly in my report, no.
- 4 Q. Do you know whether Walmart -- strike that.
- 5 Do you have any opinion whether Walmart
- 6 fulfilled its responsibility, as you described it, to
- 7 ensure that its patients had appropriate prescriptions,
- 8 true prescriptions, and prescriptions that would not harm
- 9 the patients?
- 10 A. Yes, I do.
- 11 Q. Okay. And what is your opinion?
- 12 A. I considered Walmart to be a critical actor in
- 13 the opioid supply chain, and the behavior of all the
- 14 defendants in the opioid supply chain contributed to the
- 15 oversupply that was the primary factor in driving the
- 16 current opioid epidemic. So Walmart does bear some
- 17 responsibility in the epidemic.
- 18 MR. CARTER: All right. I'll respectfully move
- 19 to strike and reask my question.
- Q. Do you know whether Walmart fulfilled its
- 21 responsibility, as you described it, to ensure that
- 22 patients had appropriate prescriptions in Nassau County
- 23 or Suffolk County?
- 24 MR. ARBITBLIT: Object to form.
- 25 THE WITNESS: I believe that Walmart did not

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- 1 fulfill its responsibility because Walmart is part of the
- 2 opioid supply chain.
- Q. BY MR. CARTER: So what patient, either a name
- 4 or a case number, did Walmart fail to fulfill its
- 5 responsibility to ensure that it was an appropriate
- 6 prescription and a true prescription in Nassau and
- 7 Suffolk County?
- A. I don't have those details.
- Q. And where in your report do you articulate the
- 10 opinion that Walmart failed to fulfill its responsibility
- 11 in those regards?
- A. I don't specifically name Walmart in my report.
- 13 Q. Same question with respect to Walgreens and CVS.
- 14 A. Same answer.
- 15 Q. Okay. You also said that pharmacists have a
- 16 responsibility to check drug interactions and
- 17 indications.
- 18 Do you recall that?
- 19 A. Yes, I do.
- 20 Q. Is that opinion reflected anywhere in your
- 21 report?

10

14 take. Sorry.

22 A. Not specifically.

6 Suffolk or Nassau counties.

8 I was asking about responsibility?

- 23 Q. And do you have any evidence that Walmart,
- 24 Walgreens or CVS failed to check drug interactions or

A. I -- pursuant to my prior response, I think that 2 applies here. To the extent that Walmart, Walgreens or

3 CVS are key in the opioid supply chain, they bear some

4 responsibility for the opioid epidemic. But I don't have 5 specific information on specific pharmacists in the

MR. ARBITBLIT: Object to form.

Q. Did I -- what in my question led you to conclude

THE WITNESS: Because your question was a 11 follow-up to my response earlier in the deposition where

Q. BY MR. CARTER: Do you have any understanding of

12 I said that pharmacists bear some responsibility and that

16 the role of community pharmacists as individual license

17 holders versus corporate policies for retail pharmacy or

18 pharmacy chains? Is that an area of your expertise?

A. I would say I'm more familiar with the 20 responsibilities of individual pharmacists, having

21 interacted with them over my 20-plus-year career.

O. Now, you also said that pharmacists play an 23 important role in educating patients about the risks and

13 there are precautions that pharmacists can make -- can

25 indications for any patient in Nassau or Suffolk County?

- 1 A. Yes, I do.
- 2 Q. Do you know how Walmart pharmacists performed

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- 3 their role of educating patients about the risks and
- 4 benefits of prescription opioids in Nassau County or
- 5 Suffolk County?
- A. No.
- Q. Have you studied that for any pharmacy defendant
- 8 in the Nassau County or Suffolk County case?
- A. No, I haven't.
- 10 Q. Do you have any knowledge of what information
- 11 pharmacists in Nassau County provide to patients at the
- 12 time of dispensing prescription opioids during the
- 13 relevant time periods for the Nassau County case?
- 14
- 15 Q. Same question for Suffolk County pharmacists.
- 16 A. Same answer.
- 17 Q. You also testified that pharmacists have a
- 18 health-safety relationship with their patients.
- 19 Do you recall that?
- 20 A. Yes.
- 21 Q. Okay. Do you have an opinion -- well, strike
- 22 that.
- 23 Does that statement appear anywhere in your
- 24 expert report for this case?
- 25 A. I don't believe so, no.

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- Page 137 Q. Do you have an opinion whether Walmart or any
- 2 pharmacy defendant violated in some way the health-safety
- 3 relationship with patients?
- A. Again, to the extent that pharmacists are an
- 5 important link in the opioid supply chain, and given the
- 6 data of overdose deaths and addiction in Nassau -- Nassau
- 7 and Suffolk counties, I think it's fair to say that every
- 8 member of that opioid supply chain failed to some extent
- 9 in their responsibilities vis-à-vis their patients and
- 10 the public in that community.
- 11 Q. And does that opinion appear anywhere in your
- 12 report?
- A. Not specifically, but I do talk at length in my
- 14 report about supply of opioids and access to opioids as a
- 15 major risk factor for addiction to opioids. I have an
- 16 entire section in my report called "The Tsunami Effect,"
- 17 which specifically refers to the rising tide of the
- 18 number of pills in the community, increasing access both
- 19 through legitimate and illicit means, putting the
- 20 population at risk.
- 21 Q. Sitting here today, are you able to assign a
- 22 numeric value, either a percentage or a raw number, of
- 23 instances in which you contend a pharmacy defendant in
- 24 Nassau County failed to fulfill the health-safety
- 25 relationship with patient-customers?

35 (Pages 134 - 137)

25

24 benefits of medications.

Do you recall that?

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- 1 A. I can't put a number on it, but I believe that
- 2 the pharmacies bear some -- some blame.
- 3 Q. Same question for Suffolk County.
- 4 A. Yeah, same answer.
- 5 Q. Do the doctors who wrote prescriptions in Nassau
- 6 County bear responsibility and some measure of blame?
- 7 A. Yes, they do.
- 8 Q. Same question for Suffolk.
- 9 A. Same answer.
- 10 Q. Okay. You also noted earlier that pharmacists
- 11 should be aware of the CDC guidelines that opioid should
- 12 not be used as first-line treatment.
- Do you recall that?
- 14 A. Yes, I do.
- 15 Q. Do you know whether any Walmart pharmacist in
- 16 Nassau County was unaware of those CDC guidelines?
- 17 A. No, I don't have information at that level of 18 specificity.
- 19 Q. Any opinion that any pharmacist for any of the
- 20 pharmacy defendants in the Nassau or Suffolk County case
- 21 was unaware of the CDC guidelines?
- 22 A. I have no specific knowledge about that.
- 23 Q. You also mentioned that pharmacists should have
- 24 good old common sense.
- Do you recall that?

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- 1 A. Yes, I do.
- 2 Q. Does that appear anywhere in your report?
- 3 A. No.
- 4 Q. Okay. Any evidence that a Walmart pharmacist in
- 5 Nassau County failed to exercise good old common sense?
- 6 A. As I answered before, the evidence as to the
- 7 absence of exercising good old-fashioned common sense is
- 8 the scourge of addiction and death due to prescription
- 9 opioids in those counties and in the state of New York
- 10 more broadly.
- 11 Q. Do you understand the pharmacy defendants are
- 12 not involved in the State of New York's case? Or do you
- 13 know that now that I said it?
- 14 A. So the defendants have changed, and so I -- I
- 15 haven't tracked exactly who's in what litigation. I'm
- 16 more broadly aware of the defendants as part of the
- 17 opioid supply chain.
- 18 Q. What aspect of common sense did a Walmart
- 19 pharmacist in Nassau County fail to exercise?
- 20 A. To the extent that there were pill mills in
- 21 Nassau and Suffolk County and a pharmacist filled
- 22 prescriptions for a pill mill doctor without trying to
- 23 make some effort to scrutinize or change the course of
- 24 that prescribing pattern, that pharmacist has
- 25 responsibility.

1 To the extent that the pharmacists in Suffolk

- 2 and Nassau County were filling prescriptions for very
- 3 high doses of opioids or for very long duration or in
- 4 combination with benzodiazepines or in combination with
- + combination with benzourazepines of in combination wi
- 5 other sedative hypnotic-type drugs, increasing that
- 6 individual's risk of accidental overdose death, that
- 7 pharmacist had some responsibility.
- 8 Q. Do either of those scenarios appear anywhere in
- 9 your report?
- 10 A. Those scenarios are implied in my report in my
- 11 discussion of the problem of oversupply, the ways in
- 12 which healthcare providers were duped based on a
- 13 misrepresentation of the science regarding the safety and
- 14 efficacy of opioids.
- 15 The evidence that I've cited in my report and in
- 16 this deposition regarding the large increase of opioids
- 17 in Nassau and Suffolk Counties, data showing that an
- 18 increase in opioid prescribing in a given geographic
- 19 region correlate with increased rates of addiction and
- 20 overdose death in those counties, that's all implied.
- 21 Also, I would just say that in my greater body
- 22 of work, including in my book and other talks I've given
- 23 and other peer-reviewed literature that I've written, I
- 24 have talked at length about not the role of pharmacists
- 25 specifically, but the role in general of healthcare

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- 1 providers vis-à-vis the epidemic.
- 2 Q. Any other evidence that those hypotheticals
- 3 actually occurred in Nassau County at a Walmart pharmacy
- 4 A. I don't have specifics on that, no.
- 5 Q. Same question for any of the pharmacy
- 6 defendants.
- 7 A. Same answer.
- 8 Q. And then same question for Suffolk County for
- 9 all pharmacy defendants.
- 10 A. Same answer.
- 11 Q. You mentioned -- and you've testified about it
- 12 before -- the idea of well-intentioned, well-meaning
- 13 physicians exercising their best medical judgement and
- 14 being duped.
- 15 Do you recall that?
- 16 A. Yes, I do.
- 17 Q. Is it fair to say that if a well-intentioned,
- 18 well-meaning physician who is setting out endeavoring to
- 19 exercise their best medical judgment under the
- 20 circumstances is duped, that there's no reason to think a
- 21 pharmacist would also -- that a pharmacist would not also
- 22 be duped?
- A. Can you rephrase the question?
- 24 Q. Sure.
- 25 If doctors were duped, do you agree that

Page 142 Page 144 1 pharmacists were duped? Q. Do you know what percentage of the pharmacy A. So I'm not familiar with the types of specific 2 market in Nassau County the pharmacy defendants 3 continuing medical education that pharmacists receive. 3 represent? 4 It's not something that I've looked into or studied. But 4 A. No, I do not. 5 I think it's plausible that if -- if doctors were duped, 5 Q. Same question for Suffolk. 6 pharmacists were also subject to the same kinds of A. Same answer. 7 misinformation, but I really haven't studied that. Q. Have you conducted any analysis to determine 8 which pharmacies in Nassau County were filling too many Q. Appreciating that you haven't studied the 9 opioid prescriptions? 9 continuing education requirements of pharmacists, based 10 on your experience as a licensed physician, do you have 10 A. No, I haven't. 11 any reason to believe that the substantive medical 11 Q. Have you conducted any analysis to determine 12 training that a pharmacist receives is more robust than a 12 which pharmacies in Suffolk County were filling too many 13 M.D.? 13 prescriptions? 14 A. I really wouldn't want to offer an opinion on 14 A. No, I have not. 15 whether or not it's more or less robust. To me, robust 15 Q. Statewide, have you conducted any analysis to 16 is a vague term. I'm not really sure what you mean. And 16 determine which pharmacies in New York state were filling 17 also, as I said, I'm not familiar with the continuing 17 too many prescriptions? 18 medical education or licensure training that pharmacists 18 A. No. 19 receive. 19 Q. In exhibit -- I believe it's C to your report, 20 you provide a testimony rate schedule, and I just wanted 20 Q. Do you think pharmacists receive more 21 substantive medical training than licensed doctors? 21 to ask you about your \$800 per hour for trial testimony. A. Uh-huh. A. I feel like I answered that. 22 23 23 Q. So you don't know one way or the other? Q. When you travel, do you bill for your time as 24 A. I don't know. 24 well or only expenses? 25 Q. So it's possible that pharmacists actually have 25 A. You mean do I bill for travel time? Page 143 Page 145 1 more in depth medical training than licensed physicians? Q. So when you travel to trial in this case, if you 1 2 MR. ARBITBLIT: Object to form. 2 testify, will you bill for your travel time? 3 THE WITNESS: They would have a different type 3 A. I will bill to be reimbursed for my travel, and 4 of training, but it could be equally in depth. 4 I will bill for my travel time as well. Q. BY MR. CARTER: Okay. You also said earlier 5 Q. If you hypothetically have to arrive in Long 6 that if someone -- if a pharmacist observed someone 6 Island on a Monday and you don't take the stand until 7 intoxicated, that should play into the pharmacist's 7 Wednesday, would you charge at your hourly rate for your 8 decision making in determining whether to dispense. 8 time waiting to testify on Monday and Tuesday? 9 9 Do you recall that? MR. ARBITBLIT: Object to form. 10 10 A. Yes, I do. THE WITNESS: No, I would not unless I spent Q. Any evidence that a pharmacy -- pharmacist at a 11 some portion of Monday or Tuesday working to prepare for 11 12 pharmacy defendant in Nassau County dispensed medication 12 the trial. 13 to an intoxicated patient? 13 Q. BY MR. CARTER: Have you submitted any invoices A. I have no specific knowledge of Nassau County in 14 for the New York cases that have not been paid? 15 15 that regard. A. Yes. 16 Q. Same question for Suffolk. 16 Q. Okay. Do you know the amount of unpaid pending 17 A. Same answer. 17 invoices? 18 Q. Do you know how many pharmacies are in Nassau 18 A. No, I do not. 19 County? 19 Q. Okay. You were asked a question earlier 20 A. No. 20 regarding the percentage of your income from your work 21 Q. Do you know how many are in Suffolk County? 21 consulting and testifying in litigation versus your work 22 22 at Stanford. You indicated you could not provide an 23 Q. Do you know how many are in the state of New 23 estimate. I want to just follow up. 24 York? 24 Do you know whether your consulting income was

25 more or less than 50 percent of your income last year?

A. No.

25

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A. I believe it was less, but it's not something

- 2 that I've actually sat down and added up and calculated.
- 3 Q. Okay. Switching gears, I want to ask you about 4 addiction.
- 5 Do you agree that, at least in theory, all
- 6 addictions can be overcome?
- 7 MR. ARBITBLIT: Object to form.
- 8 THE WITNESS: So addiction is a disease, and
- 9 just like cancer, some cases of addiction are terminal
- 10 and some are curable or can go into remission for a
- 11 period of time.

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- 12 I would say the same is true for addiction.
- 13 It's a chronic, relapsing and remitting disease. Some
- 14 people with one course of treatment can be in remission
- 15 from their addiction for the rest of their lives, and
- 16 that can mean decades.
- Other people, even with aggressive treatment,
- 18 may not be able to achieve remission and may, in fact,
- 19 die of their disease.
- 20 Q. BY MR. CARTER: In your role as someone who
- 21 treats people with substance use disorders, have you ever
- 22 approached a treatment -- a treatment of a particular
- 23 patient and advised them that they would not be able to
- 24 overcome their addiction and the treatment would not
- 25 yield productive results?

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- 1 MR. ARBITBLIT: Object to form.
- THE WITNESS: There's always room for hope. You
- 3 know, I would never deprive a patient of hope. Even if I
- 4 worked in a hospice setting where death was eminent,
- 5 there is still room for hope.
- 6 What I certainly would not do is recommend a
- 7 treatment that caused more harm than good, and I would be
- 8 very active in finding the best possible treatment for my
- 9 patient.
- 10 Q. BY MR. CARTER: And it's fair to say that absent
- 11 some kind of involuntary commitment situation, putting
- 12 that aside, it's fair to say that in general, for a
- 13 patient to quit use of a substance, break a cycle of
- 14 addiction and achieve abstinence, that requires an
- 15 intentional act on their part to try and abstain?
- 16 A. So that -- that question -- the answer to that
- 17 question is nuanced because it's very clear that in the
- 18 disease of addiction, some patients lose their capacity
- 19 for voluntary choice, meaning that even when they deeply
- 20 desire to abstain from the substance, they're not able to
- 21 abstain. Hence a residential treatment setting for
- 22 chemical dependency or addiction is an appropriate
- 23 setting for the individual who's lost their capacity for
- 24 voluntary choice.
- 25 Q. And my question was meant to be a simpler one.

1 Let me try it this way.

2 You are not able to quit on behalf of your

3 patients.

- 4 MR. ARBITBLIT: Object to form.
- 5 Q. BY MR. CARTER: True?
- 6 MR. ARBITBLIT: Object to form.
- 7 THE WITNESS: That is true.
- 8 Q. BY MR. CARTER: You've never been able to get a

- 9 patient to quit against their will, absent some kind of
- 10 involuntary commitment setting?
- 11 A. Well, again, it's important to acknowledge that
- 12 the disease of addiction is actually a disease of the
- 13 will on some level. And so when I treat addiction, I'm
- 14 trying to help a patient regain their ability for willful
- 15 choice.
- Q. And to make a quit attempt, in the general
- 17 course, a patient needs sufficient internal motivation
- 18 and external support. Fair?
- 19 MR. ARBITBLIT: Object to form.
- Q. BY MR. CARTER: To make an attempt.
- 21 A. Uh-huh. So I have seen cases of addiction where
- 22 the internal motivation is nonexistent, and yet external
- 23 encouragement can make it possible for that person to
- 24 abstain for a sufficient period of time such that they
- 25 can get their frontal lobe reengaged with their limbic
 - Page 149
- 1 system to be able to make a voluntary choice about their
 - 2 consumption of that addictive substance.3 Q. BY MR. CARTER: What is DSM-5?
 - 4 A. The Diagnostic and Statistic Manual of
 - 5 Disorders, Fifth Edition.
 - 6 Q. And how do you use that as a psychiatrist?
 - A. I use it with a grain of salt. It is an
 - 8 imperfect way to categorize mental illness. It's also to
 - 9 some extent a dictionary for communication among
 - 10 healthcare providers.
 - I do use those criteria to make diagnoses, but I
 - 12 also take other considerations into account in forming my
 - 13 treatment plan.
 - Q. So you have used the criteria, the diagnostic
 - 15 criteria and framework for an opioid use disorder as set
 - 16 forth in DSM-5; correct?
 - 17 A. Yes, I have used those criteria.
 - 18 Q. And the fifth edition was published in 2013;
 - 19 correct?
 - 20 A. I believe so.
 - Q. It followed DSM-4-TR; correct?
 - 22 A. Yes.
 - Q. And I believe you testified to this earlier, but
 - 24 fair to say that if an opioid use disorder under the
 - 25 framework articulated in DSM-5 includes a spectrum of use

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- 1 disorders?
- 2 A. That's correct.
- 3 Q. It ranges from mild, moderate to severe, for
- 4 those that have a use disorder?
- 5 A. That is correct.
- 6 Q. And is it fair to say that as a clinician
- 7 attempting a diagnosis of an opioid use disorder, you
- 8 want to see and you personally would expect a 360-degree
- 9 view of all the circumstances involved in making that
- 10 assessment of a patient?
- 11 MR. ARBITBLIT: Object to form.
- 12 THE WITNESS: Can you define what you mean by
- 13 360-degree view?
- 14 Q. BY MR. CARTER: So if you're approaching in a
- 15 clinical setting a potential diagnosis and you're
- 16 evaluating someone for an opioid use disorder, you want
- 17 to see and evaluate the full context that's available to
- 18 you in that setting?
- 19 A. Yes, I would do that.
- 20 Q. And you would consider all of the medical
- 21 history and data and patient evaluation available to you
- 22 as the clinician; correct?
- A. Yes, unless there was a piece of evidence that
- 24 was so glaring and obvious that I would not necessarily
- 25 be required to imminently rely on all the other pieces of

A. I apply my clinical judgment with a healthy dose

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- 2 of skepticism around the fact that much of the education
- 3 that I have received has been adulterated by corporate
- s that I have received has been additionated by corpora
- 4 interests. And so I really have to do an extra due
- 5 diligence and dig deeper to know what the truth is.
- 6 Q. Now, you testified earlier that data that shows
- 7 a range of 10 to 30 percent as a prevalence of somewhere
- 8 on the spectrum of an opioid use disorder for people
- 9 using opioids for chronic pain; correct?
- 10 A. Yes.
- 11 Q. I want to take the other end of that population.
- 12 So I want to use your 30 percent as the best data on the
- 13 high end and say, okay, so the other 70 percent, the
- 14 70 percent that aren't somewhere on the opioid use
- 15 disorder spectrum, is it fair to say that millions of
- 16 Americans have used opioids and not developed an opioid
- 17 use disorder?
- 18 A. That's fair to say, except that you also want to
- 19 take into account the fact that they may be at ongoing
- 20 risk for developing an opioid use disorder, even if they
- 21 haven't developed it yet.
- Furthermore, those individuals not meeting the
- 23 criteria for an opioid use disorder may nonetheless
- 24 suffer severe adverse medical consequences as a result of
- 25 their prolonged opioid therapy.

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1

- 1 information, although I would still want to gather those
- 2 over time. Which is to say I -- I may make a diagnosis
- 3 even absent a 360-degree view if there were -- was a data
- 4 point that made it very obvious.
- 5 Q. Have you ever diagnosed a patient in a clinical
- 6 setting with an opioid use disorder based on aggregate
- 7 statistics in lieu of that patient's individual clinical
- 8 presentation?
- 9 A. To some extent, yes.
- 10 Q. So you have not conducted an analysis of a
- 11 patient, not figured out their substance use history,
- 12 their pattern, and run it through the criteria of DSM-5.
- 13 Instead of that, you've relied on aggregate statistics to
- 14 make a diagnosis.
- 15 Is that --
- 16 MR. ARBITBLIT: Object to form.
- 17 THE WITNESS: No, that's -- that's not correct.
- 18 I don't rely on aggregate statistics to make that
- 19 diagnosis. But I do allow the reading of the science to
- 20 inform my interpretation of the specific clinical data
- 21 that I gather on a patient.
- 22 Q. BY MR. CARTER: You apply your clinical judgment
- 23 and medical training which includes all of the
- 24 constellation of factors that you've considered in the
- 25 course of your work and education; correct?

- So it's essential that we, as healthcare
- 2 providers, do a careful risk-benefit assessment informed
- 3 by the unique patient history, as well as the evidence
- 4 showing that there is no robust or reliable data for
- 5 long-term efficacy of opioids and then enormous risk in
- 6 continuing opioids long-term.
- 7 Q. But to the -- to the basic statistical point,
- 8 you agree that as a matter of arithmetic, there are
- 9 millions of Americans who have taken opioids for chronic
- 10 pain and not developed, to this point in time, some
- 11 version of an opioid use disorder?
- 12 MR. ARBITBLIT: Object to form.
- 13 THE WITNESS: Well, I agree as a matter of
- 14 statistics that there are millions of Americans who have
- 15 not necessarily developed an opioid use disorder, but
- 16 those individuals are still at high risk, and that's the
- 17 point that I'm trying to make.
- 18 Q. BY MR. CARTER: Okay. Do you agree that there
- 19 are millions of Americans who have used opioids for
- 20 chronic pain and not gone on to take any kind of illegal
- 21 drug?
- A. Yes, I agree.
- Q. Do you agree that there are millions of
- 24 Americans who have taken opioids for chronic pain and not
- 25 committed any crime related to obtaining substances?

Page 154 Page 156 1 A. Yes. 1 Q. Is that a "yes"? 2 MR. CARTER: Okay. I'm going to mark as 2 A. Yes, you read that correct. 3 Exhibit 6, a page from DSM-5. This is the one I already Q. Now, when you look at the statistic DSM-5 4 premarked. 4 quotes, the first one we read, the 0.37 percent that's an (Exhibit 6, Opioid Use Disorder, DSM-5, page 5 American statistic, that falls within the 0.36 and 0.44 6 543, marked for identification.) 6 numbers that are the average prevalence for the European 7 Q. BY MR. CARTER: Now, after DSM provides the 7 Union and Norway; correct? 8 criteria for diagnosis, it also includes statistics and A. Yes. 9 commentary about the framework for the various diagnoses 9 Q. Okay. Have you ever written to the American 10 contained within it; correct? 10 Psychiatric Association suggesting revisions or 11 A. Yes. 11 corrections to DSM-5? 12 O. And I want to ask you about the highlighted 12 A. No, but it's a good idea. 13 language on page 543 under the heading "Prevalence." The Q. Okay. So do you dispute the numbers -- well, 14 first sentence: "The 12-month prevalence of opioid use 14 let's take each of these in -- in part. 15 disorder is approximately 0.37 percent among adults age 15 Do you dispute the 12-month prevalence of opioid 16 18 and older in the community population." 16 use disorder of 0.37 percent for Americans age 18 and 17 Did I read that correctly? 17 older? 18 A. Yes. 18 A. Can I read this document before I answer? 19 O. I want to read the next sentence. 19 O. Sure. MR. ARBITBLIT: Before you do, I just want to 20 20 A. Okay. 21 put an objection to the incomplete document that's being 21 (Interruption in proceedings.) 22 provided. THE WITNESS: Okay. Yes. Thank you. 22 23 MR. CARTER: That's fine. 23 Q. BY MR. CARTER: So my question is: Do you 24 MR. ARBITBLIT: And the lack of the references 24 dispute the number in the first paragraph under 25 that DSM-5 undoubtedly cites elsewhere in the document 25 prevalence reported for 12-month prevalence in America? Page 155 Page 157 A. So I would really like to see what they base 1 that you have not provided. Q. BY MR. CARTER: Okay. You have a copy of DSM-5, 2 these numbers on. That would be a good place to start. 3 And if I could review those, then I would have more to 3 Doctor; correct? 4 A. I do. 4 say. 5 But in general, I -- I believe that reliable Q. The second sentence --5 6 sources quote about 2 to 4 million Americans have an 6 A. But not right here with me. 7 Q. Yes. 7 opioid use disorder in this country, with some reports as 8 high as 15 million Americans with opioid use disorder "This may be an underestimate because of the 9 when you included marginalized populations like 9 large number of incarcerated individuals with opioid use 10 incarcerated individuals, which was not done for this 10 disorders." 11 calculation. 11 Did I read that correctly? 12 12 Q. Okay. Thank you. A. Uh-huh. Q. All right. Then I want to read from the last 13 A. Yeah. 14 Q. You can put that aside. 14 paragraph in that section that makes a comparison to 15 A. Okay. 15 Europe. 16 "The 12-month prevalence of problem opioid use 16 Q. Have you analyzed the medical examiner overdose 17 death data from Nassau County? It's not in your list of 17 in European countries in the community population ages 15 18 sources, but... 18 to 64 years is between 0.1 percent and 0.8 percent." 19 A. Yes. It's not in my list of sources, but I did 19 Did I read that correctly? 20 A. Uh-huh. 20 review the Keyes reports, which does analyze some Q. The next sentence reads: "The average 21 overdose death data, and I did include on page -- sorry, 22 let me find the page. 22 prevalence of problem opioid use in the European Union 23 and Norway is between 0.36 percent and 0.44 percent." 23 Q. I'll withdraw the question and ask you a similar 24 one. 24 Did I read that correctly? 25 25 A. Uh-huh. A. Okay.

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- 1 Q. Do you have an opinion in this case as to the
- 2 number or the identities of any particular case numbers
- 3 in Nassau County where a decedent was diagnosed with an
- 4 opioid use disorder?
- A. No.
- 6 Q. Any such opinion for Suffolk County?
- 7 A. No.
- 8 Q. Are you able to look at the medical examiner's
- 9 chart of reported deaths and individually diagnose the
- 10 subjects referenced there with an opioid use disorder
- 11 during the course of their life?
- 12 A. Are you asking me if I have done that or if I
- 13 would be able to do that?
- 14 Q. So first question: Have you?
- 15 A. I have not.
- 16 Q. And that applies to Suffolk County as well?
- 17 A. That's correct.
- 18 Q. Okay. Looking at an autopsy report that lists
- 19 toxicology at time of death, does that information by
- 20 itself provide an individual's substance use history?
- 21 A. It might be indicative, but probably in and of
- 22 itself not sufficient.
- 23 Q. Is there a posthumous test for addiction or an
- 24 opioid use disorder?
- 25 A. So the diagnosis of addiction, there's no

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- Q. To your knowledge, do any of the doctors that
- 2 you encountered in the setting you described practice in
- 3 Nassau County?
- 4 A. I don't know.
- 5 Q. Do you know whether any of those doctors
- 6 practice in Suffolk County?
- 7 A. I don't know.
- 8 Q. Okay. Have you interviewed any employee of
- 9 Nassau County or Suffolk County for purposes of forming
- 10 your opinions in this case?
- 11 A. No.
- 12 Q. Have you interviewed any resident of Nassau
- 13 County or Suffolk County for purposes of forming your
- 14 opinions in this case?
- 15 A. No.
- 16 Q. Have you interviewed any law enforcement
- 17 personnel in Nassau County or Suffolk County for purposes
- 18 of forming your opinions in this case?
- 19 A. No.
- Q. Have you interviewed any community pharmacists
- 21 in Nassau County or Suffolk County for purposes of
- 22 forming your opinions in this case?
- 23 A. No.
- Q. And taking out the qualifier of purposes of
- 25 forming your opinion, have you ever interviewed a

- 1 biological test for that. There's not a brain scan or
- 2 blood test. It's the accumulation of multiple sources of
- 3 evidence based on behaviors, but not just patient
- 4 self-report, other objective data of their behavior,
- 5 including potentially a coroner's report indicating what
- 6 substances were in their system at the time of death.
- 7 Q. Are you aware of any specific case in Nassau
- 8 County where an individual only ever used opioids as 9 directed under the care of a physician in the amount
- 10 directed and yet died of an overdose from that prescribed
- 11 opioid?
- 12 A. I'm not aware of cases like that in Suffolk or
- 13 Nassau counties, but I am aware of cases like that in my
- 14 own medical experience.
- 15 Q. Okay. I want to ask you a couple questions
- 16 about materials you considered.
- 17 Have you interviewed any doctor practicing in
- 18 Nassau County for purposes of offering your opinions in
- 19 this case?
- 20 A. I haven't interviewed -- I haven't set out to
- 21 interview doctors specifically for the purposes of this
- 22 litigation, but I have traveled to New York and talked to
- 23 doctors who have experiences, and based on those
- 24 conversations, I have gathered knowledge about the
- 25 situation in New York.

- Page 161
 1 community pharmacist in Nassau County or Suffolk County,
- 2 to your knowledge?
- 3 A. No.
- 4 Q. Do you know how the opioid crisis in Nassau
- 5 County in 2020 compares to the situation in 2015?
- 6 A. So the opioid epidemic, including in the state
- 7 of New York, has heavily impacted the foster care system.
- 8 Q. And just to be clear, I want to just remind you
- 9 I'm only focused on Nassau County, and then I'll have a
- 10 separate question for Suffolk.
- 11 A. Okay.
- 12 Q. If that can guide your answer, I'd appreciate
- 13 it.
- 14 A. Okay. Well, I don't have data specific to
- 15 Nassau or Suffolk County in my report and in my answer,
- 16 but I do have for the State of New York.
- 17 Q. Okay. Since I'm not -- my client's not in the
- 18 New York case, I'll let others ask you about broader New
- 19 York data.
- 20 A. Okay.
- Q. Switching gears, is it fair to say that the
- 22 majority of prescriptions for opioids in Nassau and
- 23 Suffolk County were made in good faith for a legitimate
- 24 medical purpose?
- MR. ARBITBLIT: Object to form.

Page 162 1 THE WITNESS: I would not want to opine on 1 into believing that opioids are safe and effective 2 whether it was the majority or the minority of 2 treatment, when, in fact, they are not safe and effective 3 prescription opioids that have -- I -- I -- it is both 3 for the purposes of chronic and minor pain conditions. 4 the prescriptions made in good faith and prescriptions Q. BY MR. CARTER: Were such prescriptions, as you 5 made not in good faith that have contributed to the 5 described them, filled and dispensed by pharmacists 6 opioid epidemic across this, country including in Suffolk 6 acting in good faith? 7 and Nassau County, which I do not believe are rare or 7 MR. ARBITBLIT: Object to form. 8 unusual or differ in any substantial way from the rest of 8 THE WITNESS: I would really have to look at the 9 the United States. 9 specifics of the actions of a given pharmacy and a given 10 Q. BY MR. CARTER: Without asking you to give a 10 pharmacist to be able to make that determination. 11 qualitative comparison in terms of majority or minority, Q. BY MR. CARTER: And you have not done that work 12 do you agree that there are -- there were hundreds of 12 and therefore do not have any such opinion for this case. 13 thousands of prescriptions for opioids in Nassau and 13 Fair? 14 Suffolk counties that were made in good faith for a A. Well, I do have an opinion, which I've 15 legitimate medical purpose? 15 expressed, but I haven't done that specific work on a 16 MR. ARBITBLIT: Object to form. 16 specific pharmacy or a specific pharmacist in those 17 THE WITNESS: I would agree that many of the 17 counties. 18 prescriptions for opioids that actually led to harm, both Q. Sitting here today, can you tell me either a 18 19 in individuals to whom they were prescribed as well as 19 number or percentage of prescriptions for opioids that 20 other individuals who became exposed to opioids through 20 the pharmacy defendants in this case should have refused 21 the oversupply, were made in good faith by the 21 to dispense in Nassau County? 22 prescribing physician. 22 A. I think the way that you framed the question Q. BY MR. CARTER: And there were also 23 simplifies the problem. So it's not just a matter of 24 prescriptions that did not lead to harm that were made in 24 pharmacists refusing to fill a prescription; it's a 25 good faith by the prescribing physician? 25 matter of pharmacists doing their due diligence to Page 163 1 A. I think it's a minority of those prescriptions 1 determine whether or not the risks outweigh the benefits 2 that did not lead, that has not lead, that is not 2 for a given prescription. And I think in general, across 3 continuing to lead to some degree of harm. 3 the opioid supply chain, that kind of due diligence has 4 Q. But they do exist? 4 been absent. 5 A. They do exist in very rare circumstances. 5 Q. Let me reask my question. Q. In this case, do you have an opinion as to any Are you able to opine and provide either a 7 specific number of prescriptions for opioids filled in 7 specific number or a specific percentage of prescriptions 8 the Nassau or Suffolk County that were not for a 8 for opioids that you believe a pharmacy defendant should 9 legitimate medical purpose? 9 not have dispensed in Nassau County? 10 MR. ARBITBLIT: Object to form. 10 MR. ARBITBLIT: Object to form. 11 THE WITNESS: I do not have a specific number. 11 THE WITNESS: I'm not able to provide a specific 12 Q. BY MR. CARTER: Do you have a specific 12 number or a specific percentage, but I have a qualifier, 13 percentage? 13 if that's okay. 14 MR. ARBITBLIT: Object to form. But, again, I do think that it's not as simple 15 THE WITNESS: Percentage wise, I would opine 15 as refusing to dispense. And a large part of my work, 16 that the large majority of prescriptions written for 16 especially in the past three to four years, has 17 opioids in Suffolk and Nassau County were not, in fact, 17 emphasized the need for compassionate tapers. We have 18 written for legitimate medical purposes, but not because 18 created several generations of individuals, pain patients 19 the physicians were -- were in any way practicing outside 19 who are now physiologically dependent on opioids and

21

25 iatrogenic harm.

20 should not be abruptly discontinued.

So I think an effective intervention here is not

23 and figure out how we can safely and compassionately care

24 for several generations of Americans who have suffered

22 simply to refuse to dispense, but it's to come together

20 of what they had been taught. Let me rephrase that.

22 those counties, as sort of broadly representing the

23 phenomenon in the United States, have been written for

24 what doctors thought was a legitimate purpose, but in

25 fact was not a legitimate purpose, that they were duped

The majority of opioid prescriptions written in

Page 166 Page 168 1 Q. BY MR. CARTER: Sitting here today, are you able 1 excluded by a Court from testifying as an expert 2 to provide an opinion regarding the number or a specific 2 regarding marketing causation? That is, any effect 3 percentage of prescriptions for opioids that a pharmacy 3 defendants' marketing efforts may have had on the supply 4 defendant should have refused to dispense in Suffolk 4 or sales of opioids? 5 County? A. I do believe in the MDL it was determined that I A. Same answer as before. 6 do not have marketing expertise and so should not opine 7 Q. Okay. Have you ever worked with Dr. Judith 7 on direct causation, but I would qualify that by saying 8 that I do have expertise on the extent to which 8 Prochaska? A. Yes. 9 scientific evidence has informed or failed to inform the 10 Q. Have you spoken to her about your testimony in 10 marketing material of defendants in this case. 11 this case? 11 Q. And have you read the opinion excluding you from 12 A. Not at any level of detail. 12 offering those opinions? 13 Q. Have you spoken to her about testifying in 13 MR. ARBITBLIT: Object to form. Vague, "those 14 opinions." 14 trials on behalf of plaintiffs? 15 A. I may have mentioned that I've been retained as THE WITNESS: Yes. So could you --16 an expert witness, but not -- not any specifics beyond 16 Q. BY MR. TSAI: Those opinions that I've referred 17 that. 17 to, that you've agreed that you have been excluded from 18 Q. Are you familiar with Dr. Robert Proctor from 18 testifying as an expert about. 19 the history department at Stanford? 19 MR. ARBITBLIT: Object to form. 20 20 A. Yes. Do you have the order? 21 Q. Have you ever spoken to him about testifying for 21 MR. TSAI: (Shakes head.) 22 plaintiffs in litigation? 22 THE WITNESS: So I guess could you repeat the 23 A. No. 23 question? 24 Q. Okay. Have you spoken to him about your 24 Q. BY MR. TSAI: Yes. 25 opinions and work in the area of opioids? 25 Have you read the order that you referred to the Page 167 Page 169 1 national MDL excluding you from testifying regarding 1 A. No, I have not. 2 MR. CARTER: Those are all the questions I have, 2 marketing conditions? A. Yes, I have read that order. But I would say 3 time permitting. I'll just note for the record I do have 3 4 additional questions, but subject to the Court's 4 that it --5 limitations, I have to tender the witness at this time. 5 MR. TSAI: You know, I think that we've got a 6 So I just have an objection on that basis. 6 limited time. Let -- the admonition directly from the 7 Thank you for your time, Doctor. 7 Court is answer the question. Don't offer additional 8 THE WITNESS: You're welcome. 8 opinions. So I'd like to move on. 9 THE VIDEOGRAPHER: Off the record again? Q. Do you have any degrees or training in 10 MR. CARTER: Yes, please. 10 pharmacoeconomics? 11 THE VIDEOGRAPHER: Going off the record, the 11 A. No. 12 time is 1:15 p.m. 12 Q. Do you teach any courses on the econometrics of 13 sales or marketing? 13 (Recess.) 14 (Mr. Pyser leaves deposition room.) 14 15 THE VIDEOGRAPHER: Back on the record, the time 15 Q. Do you have any degrees or training in the 16 is 1:23 p.m. 16 econometrics of sales or marketing? 17 **EXAMINATION** 17 A. No. Q. BY MR. TSAI: Good afternoon. 18 18 Q. Do you have any degrees or training in marketing 19 A. Good afternoon. 19 statistics? 20 Q. Very good to see you again. 20 A. No. 21 21 Q. Do you have any employment experience working in 22 Q. One of these days we should chat more about your 22 the field of pharmaceutical marketing? 23 23 Chinese language skills. A. No. 24 24 A. Uh-huh. Q. Do you belong to any professional associations

25 in the field of pharmaceutical marketing?

Q. So just diving right in, have you ever been

25

Page 170 Page 172 1 not have a specific sales force for their generics, but 1 A. No. 2 Q. Have you ever worked for the DA? 2 most of the opioid manufacturers' defendants in this case 3 MR. ARBITBLIT: The DA? 3 had a combination of branded and generic opioids, and the 4 O. BY MR. TSAI: DEA. 4 generic -- and the marketing that those defendants did 5 5 for their branded opioids augmented sales and influenced 6 Q. Have you ever consulted for the DEA? 6 sales in prescribing of their generic opioids. 7 A. I have done some unpaid consulting for the DEA. Q. Are you aware of any -- can you identify any 8 Q. Oh. When was that? 8 defendant maker of generic opioids with a sales force in 9 A. That was just last week. 9 New York? 10 Q. Okay. And what was the nature of that 10 A. I don't know specifics on their sales forces in 11 consulting? 11 New York. I would assume that all of the defendants have 12 A. A DEA agent in Oakland who does undercover work 12 deployed a sales force in New York state. 13 to try to figure out whether doctors in that area are Q. Sorry. I meant with respect to their portfolio 14 of generic medicine specifically. 14 engaging in safe opioid prescribing consulted me about 15 MR. ARBITBLIT: Object to form. 15 what an evidence-based evaluation of a patient should 16 16 look like, and I spent about an hour on the phone with THE WITNESS: Could you rephrase your question? 17 him. 17 Q. BY MR. TSAI: Sure. 18 Q. Okay. How many conversations did you have with 18 Identify a defendant maker of generics that had 19 that DEA agent in Oakland? 19 a sales force for those generic opioids in New York. 20 20 A. I am assuming, although I don't know for sure, A. One. 21 Q. Okay. Other than that conversation, have you 21 that all of the defendants had a sales force for opioids 22 consulted for the DEA? 22 in the state of New York. 23 23 Q. And by "opioids," you're referring to a sales A. No. 24 Q. Have you ever designed a suspicious order 24 force for their branded products; correct? 25 monitoring program? 25 A. Yes. But as I said, their marketing for branded Page 171 Page 173 1 A. No. 1 products also impacted the sales of generics. Q. Do you hold yourself out as an expert in the Q. You did no regression analysis to isolate the 3 design or implementation of DEA registrant suspicious 3 impact on sales that any opioid marketing by any 4 order monitoring? 4 individual defendant had on New York doctors and nurses; A. I think that I could offer an informed opinion 5 is that correct? 6 on what suspicious orders might look like based on my A. I did no personal regression analysis. 7 clinical experience and my knowledge of addiction. 7 Q. Okay. You did not conduct any analysis to Q. Do you consider that informed opinion to be 8 isolate which individual prescribers in New York 9 expertise in the -- the design and implementation of a 9 purportedly relied upon any alleged marketing by any 10 DEA registrant's suspicious order monitoring systems? 10 individual defendant; correct? A. I think as a front-line clinician working with 11 MR. ARBITBLIT: Object to form. 12 people with opioid addiction and as somebody who has 12 THE WITNESS: On a national scale? 13 researched the opioid epidemic, I could be a useful 13 Q. BY MR. TSAI: Again, answer the question. I 14 source of knowledge in designing such a system. 14 limited this to New York. 15 15 Q. Are you familiar with the concept of sameness in MR. ARBITBLIT: Object to form. 16 the context of sales of generic medicines? 16 THE WITNESS: I believe that most prescribers in A. If by "sameness" you mean that drugs are 17 17 New York were the recipients of the misleading 18 pharmacologically similar and act in a similar way. Is 18 promotional messages of opioid manufacturers in New York 19 that what you mean by "sameness"? 19 state, and I base that on my discussions -- I base that 20 Q. Is that your understanding of what that term 20 in part on my discussions with doctors in the state of 21 "sameness" means in the context of generic medicines? 21 New York in my travels there. 22 A. That would be my guess as to what it means. O. BY MR. TSAI: You know, the directive from the 23 Q. Are you aware that makers of generic opioids did 23 Court is you must be direct and not evade, answer the 24 not have a sales force for those generic medicines? 24 question. Otherwise, we'll be back here.

So I asked you very specifically about New York

25

A. I am aware that makers of generic opioids did

1	and about individual prescribers and individual	

- 2 defendants. So let me ask again, and if I could please
- 3 receive an answer to that question.
- 4 You did not conduct any analysis to isolate
- 5 which individual prescribers in New York purportedly
- 6 relied upon any alleged marketing by any individual
- 7 defendant; is that correct?
- 8 MR. ARBITBLIT: Object to form and object to
- 9 badgering and object to the precursor to the question.
- 10 THE WITNESS: I did not conduct individual
- 11 analysis of specific prescribers in the state of New
- 12 York.
- 13 Q. BY MR. TSAI: Did you conduct any actual survey
- 14 specific to New York regarding pharmaceutical marketing
- 15 that was seen or heard or otherwise communicated to
- 16 doctors or patients in New York?
- 17 A. I have had discussions with doctors in the state
- 18 of New York who have told me that they've been the
- 19 recipients of the same misleading promotional messages as
- 20 all the rest of us have for the past three decades and --
- 21 and also the statistics on addiction rates and deaths in
- 22 the state of New York mean that New York is not somehow a
- 23 exception on a national level in terms of this opioid
- 24 epidemic.
- 25 And so that leads me to conclude that

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1 Q. Have you done any analysis yourself quantifying

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- 2 the contribution in your opinion of that company to the
- 3 opioid situation in New York?
- 4 A. I have not quantified the contribution, nor do I
- 5 think that it's my role to quantify the contribution.
- Q. Okay. And you have not quantified the
- 7 contribution, nor do you believe it's your role to
- 8 quantify the contribution, with respect to any defendant
- 9 in this case.
- 10 Is that fair to say?
- 11 MR. ARBITBLIT: Object to form.
- 12 THE WITNESS: Well, I would quantify -- I would
- 13 quantify the contribution of the defendants in this case
- 14 by saying that without their actions, I believe the
- 15 opioid would not have occurred.
- 16 Q. BY MR. TSAI: Okay. So that's a general opinion
- 17 as to all defendants as a group, fair to say?
- 18 A. That's correct.
- 19 Q. So just to be clear, you have not done any
- 20 analysis yourself quantifying the contribution in your
- 21 opinion of any specific defendant business to the opioid
- 22 situation in New York; is that correct?
- 23 A. Yes.
- Q. You believe that others, let's say outside the
- 25 circle of what you say is the opioid pharmaceutical

- 1 prescribers in the state of New York were also duped in
- 2 terms of their understanding of the evidence base
- 3 regarding the use of opioids in the treatment of pain.
- 4 Q. And that wasn't my question.
- 5 So you conducted no comprehensive survey of
- 6 doctors and nurses in New York to understand what
- 7 marketing materials, if any, prescribers in New York
- 8 received from what individual defendant; is that correct?
- 9 MR. ARBITBLIT: Object to form.
- 10 THE WITNESS: I feel like I answered your
- 11 question to the best of my ability.
- 12 Q. BY MR. TSAI: So do you have a survey that you
- 13 can show us where you surveyed doctors and nurses in New
- 14 York regarding asking them for, for example,
- 15 Mallinckrodt, what specific marketing materials did you,
- 16 Dr. Smith in Nassau, receive from Mallinckrodt? Do you
- 17 have that to produce?
- 18 MR. ARBITBLIT: Object to form.
- 19 THE WITNESS: I don't have a survey at that
- 20 level of specificity.
- 21 Q. BY MR. TSAI: Okay. And just to confirm, even
- 22 though you've deleted Purdue from your report in this
- 23 case, in your opinion, do you still consider Purdue as a
- 24 contributor to the opioid situation in New York?
- 25 A. Yes, I do.

- Page 177 1 industry, others bear some responsibility for the opioid
- 2 epidemic; is that correct?
- 3 A. That is correct.
- 4 Q. Okay. Can you show me where in your methodology
- 5 you quantified the extent to which those other persons
- 6 and entities bear responsibility for the opioid epidemic
- 7 in New York?
- 8 MR. ARBITBLIT: Object to form.
- 9 THE WITNESS: I don't specifically quantify the
- 10 responsibility of those other entities, but I do make it
- 11 very clear that the opioid pharmaceutical industry,
- 12 namely, the defendants, took advantage of some of the
- 13 structural problems inside medicine to leverage their
- 14 push for an increase in opioid prescribing.
- 15 And I do also make it clear that although others
- 16 are responsible, without the actions of the opioid
- 17 pharmaceutical industry, I do not believe this opioid
- 18 epidemic would have occurred, whereas those other
- 19 entities, their actions might still have occurred, and I
- 20 don't think it would have led to the crisis that we have 21 today.
- In other words, the actions of defendants have
- 23 been instrumental.
- Q. BY MR. TSAI: So let me complete this concept.
- So in your methodology, there is no place you

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- 1 can point to, for example, where you quantify the extent
- 2 to which government policies caused or contributed to the
- 3 opioid epidemic in New York.
- 4 Is that fair to say?
- 5 MR. ARBITBLIT: Object to form, misstates the 6 record.
- 7 THE WITNESS: I don't specifically quantify, but
- 8 I do a lot of qualitative analysis and have done
- 9 qualitative analysis, both in the writing of my book and
- 10 in forming my opinion. And in my qualitative analysis, I
- 11 have apportioned responsibility, pivotal responsibility,
- 12 to the actions of the defendants.
- 13 Q. BY MR. TSAI: But no portion of your methodology
- 14 where you can point to where you quantify the degree of
- 15 responsibility that you would allocate to government
- 16 policies?
- 17 MR. ARBITBLIT: Object to form.
- 18 THE WITNESS: I don't give it a number, no.
- 19 Q. BY MR. TSAI: Okay. Same question with respect
- 20 to the extent to which managed care or reimbursement
- 21 policies caused or contributed to the opioid epidemic in
- 22 New York.
- 23 MR. ARBITBLIT: Object to form.
- 24 THE WITNESS: I don't give it a number, no.
- 25 Q. BY MR. TSAI: Same questions with respect to

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- 1 Q. BY MR. TSAI: Okay. You said many. I just want 2 to be clear.
- 3 Do you believe that every factor that you have
- 4 said others bear some responsibility for the opioid
- 5 epidemic, every contributing factor is attributable to
- 6 what you call the opioid pharmaceutical industry?
- 7 MR. ARBITBLIT: Object to form.
 - THE WITNESS: If not attributable, then actively
- 9 exploited by the defendants to increase the supply of 10 opioids.
- 11 Q. BY MR. TSAI: So let me just make the record and 12 continue.
- 13 Is there any part of your methodology you can
- 14 point to where you quantified the extent to which health
- 15 insurance companies dictated whether and which patient
- 16 was prescribed opioids and therefore contributed to the
- 17 opioid epidemic in New York?
- 18 MR. ARBITBLIT: Object to form.
 - THE WITNESS: So in my report, I do reference an
- 20 article on page 5 of the "Use of Opioid Agonist Therapy."
- 21 And this article specifically looks at opioid prescribing
- 22 among Medicare Part D patients and notes that at that
- 23 time, Medicare Part D, for example, did not cover
- 24 prescriptions for -- give me a moment -- methadone
- 25 maintenance in the treatment of opioid use disorder, and

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19

- 1 quantifying the extent to which formulary coverage had an
- 2 impact on the opioid epidemic in New York.
- 3 MR. ARBITBLIT: Object to form.
- 4 THE WITNESS: So again, all of those
- 5 contributing factors that appear, as you were phrasing
- 6 the questions, to be separate from the actions of the
- 7 defendants were actually heavily influenced by the
- 8 lobbying efforts of the defendants.
- 9 So it's difficult for me to isolate and quantify
- 10 the contributing responsibility of those separate
- 11 factors, when those factors are not, in fact, separate
- 12 from the actions of the defendants. And I talk about
- 13 that in my report.
- 14 Q. BY MR. TSAI: Okay. So, again, just to ask the
- 15 question, I'm asking you to answer it.
- 16 A. Yeah.
- 17 Q. You did not isolate the extent to which, in your
- 18 opinion, formulary coverage was responsible for the
- 19 opioid epidemic in New York; is that correct?
- 20 MR. ARBITBLIT: Object to form.
- 21 THE WITNESS: So I didn't isolate it because I
- 22 don't believe it's isolateable. I believe that many of
- 23 these structural factors inside and outside of medicine
- 24 were, in fact, influenced by the opioid pharmaceutical 25 industry.

- Page 181 1 that although Medicare Part D did cover
- 2 buprenorphine/naloxone for the treatment of opioid use
- 3 disorder, the whole message, or one of the major messages
- 4 of that article was to opine on the fact that what a --
- 5 what a third-party payor like Medicare will cover does
- 6 influence how that medication is prescribed.
- 7 Q. BY MR. TSAI: Okay. So let me switch gears and
- 8 let me make it a little more interesting.
- 9 Let me ask you just agree or disagree, in your 10 opinion.
- 11 So agree or disagree in your opinion with this
- 12 proposition: Proper assessment of the patient, proper
- 13 prescribing practices, periodic reevaluation of therapy,
- 14 and proper dispensing and storage are appropriate
- 15 measures to help limit abuse of opioid drugs.
- 16 A. Yes, those are appropriate measures, but
- 17 probably not in and of themselves sufficient.
- 18 Q. Same question. Agree or disagree in your
- 19 opinion with this proposition: Concerns about abuse,
- 20 addiction and diversion should not prevent the proper
- 21 management of pain?
- A. Implied in your question is that the proper
- 23 management of pain involves prescribing opioids, and I
- 24 would say, especially when it comes to chronic pain, that 25 is not true, and that the proper management of chronic

Page 182 1 pain would be expressly to avoid the prescribing of

- 2 opioids in the vast majority of cases. Because the
- 3 evidence is very convincing that opioids used long-term
- 4 don't work and may even make the pain worse.
- Q. Okay. Just to clarify, let's talk about the
- 6 specific context of prescribing an opioid for someone who
- 7 is showing long-term pain, telling her doctor she has
- 8 long-term pain.
- In your opinion, would saying to a doctor,
- 10 "Concerns about abuse, addiction and diversion should not
- 11 prevent the proper management of pain," is that
- 12 misleading, in your opinion?
- 13 MR. ARBITBLIT: Object to form.
- 14 THE WITNESS: Yes, that is misleading in my
- 15 opinion, yeah.

1 long-term use.

- Q. BY MR. TSAI: Okay. Agree or disagree in your
- 17 opinion with this proposition: The potential for these
- 18 risks of opioid addiction, abuse or misuse should not
- 19 prevent the prescribing of opioids for the proper
- 20 management of pain in any given patient?
- 21 MR. ARBITBLIT: Object to form.
- 22 THE WITNESS: I would really need you to qualify
- 23 your question regarding more specifically the nature of
- 24 the pain condition, the prognosis of the individual,
- 25 whether opioids were being recommended for short or

But to more broadly respond, I do think that the

Q. BY MR. TSAI: So is it fair to say -- this is my

7 understanding of your response, is that it depends on the

3 risk of opioid addiction and misuse should be front and

4 center in that healthcare provider's thoughts when

8 clinical context, things like the nature of the

9 condition, the prognosis of the specific patient, the

11 to opine whether that statement that I just -- that

12 proposition that we just discussed, stating that to

MR. ARBITBLIT: Object to form.

16 listed are certainly important in the consideration of

17 prescribing opioids, but are not in and of themselves

THE WITNESS: So the list of topics that you

The prescriber must also take into account the

20 broader context of the problems of abuse and diversion,

21 especially now in the United States, given the scourge of

So it's not just the individual care of that

24 patient, although very, very important. We also have to

25 take into account the Public Health and population level

22 addiction and death, the opioid epidemic.

10 type of opioid, whether it's short-term, long-term, to --

5 considering an opioid prescription.

13 doctors would be improper?

14

15

19

23

18 sufficient.

- Page 184
- 2 judgment for how to prescribe the opioid based on true
- 3 and reliable scientific evidence.
- O. BY MR. TSAI: So let me just read that

1 health. As well as -- as well as be able to form

- 5 proposition again.
 - The potential for these risks of opioid
- 7 addiction use or misuse should not prevent the
- 8 prescribing of opioids for the proper management of pain
- 9 in any given patient.
- 10 Do you think that that's an accurate statement?
- 11 MR. ARBITBLIT: Object to form.
- 12 THE WITNESS: Could you do me a favor? Because
- 13 I want to make sure I accurately understand your
- 14 question. Could you just say the proposition --
- Q. BY MR. TSAI: Uh-huh, yes. 15
- 16 A. That you want me to --
- 17 Q. Yes.
- 18 A. Okay. Thank you.
- 19 Q. The potential for these risks of opioid abuse,
- 20 addiction and misuse should not prevent the prescribing
- 21 of opioids for the proper management of pain in any given
- 22 patient?
- 23 MR. ARBITBLIT: Object to form.
 - THE WITNESS: I disagree with that.
- 25 Q. BY MR. TSAI: Okay. If it were up to you, would

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24

- 1 you recommend that prescription opioid medications be
- 2 taken off the market?
- A. Of course not.
- Q. Okay. Would you ban prescription opioids for
- 5 all pain conditions?
- A. Of course not.
- Q. Would you ban the prescription of opioid
- 8 medications for all pain conditions involving non-cancer
- 9 pain?
- 10 A. Of course not.
- 11 Q. Okay. Would you recommend banning opioid
- 12 medications for the treatment of conditions involving
- 13 chronic non-cancer pain?
- 14 A. Of course not.
- Q. Okay. So again, agree or disagree with this 15
- 16 proposition: There are some people for whom chronic
- 17 opioids for pain work?
- A. I would say the scenario in which chronic
- 19 opioids for chronic pain are more helpful than harmful is
- 20 a very rare scenario, and in my professional experience,
- 21 I have seen more harm than good come from chronic opioid
- 22 therapy, plus the evidence does not support the use of
- 23 opioids in the treatment of chronic pain. All reliable
- 24 studies show that opioids are no better than Tylenol or 25 Ibuprofen, with many more incurred risks, and that the

Page 186 1 risk of addiction and overdose death increases with

- 2 increasing dose and duration of the opioid therapy.
- Q. All right. This sounds a lot like commenting on 4 something I didn't ask.
- Let me ask you very quickly again, do you
- 6 personally believe that there are people in the United
- 7 States and New York for whom chronic opioids work, for
- 8 which the benefit outweighs the harm?
- MR. ARBITBLIT: Objection. And since counsel is
- 10 insisting on putting his preface before the question,
- 11 which is inappropriate, I'll put mine in, which is that
- 12 you've answered the question. If you have anything to
- 13 add, you're free to do so.
- 14 THE WITNESS: I do think I answered the 15 question.
- 16 Q. BY MR. TSAI: So is it a "yes," there are people
- 17 for whom chronic opioids work?
- 18 MR. ARBITBLIT: Object to form.
- 19 THE WITNESS: I am willing to consider the
- 20 possibility that there is a very small group of
- 21 individuals for whom the benefit of long-term opioids may
- 22 be slightly better than placebo. But as time goes on, I
- 23 think the incurred risks for the vast majority of
- 24 individuals will outweigh any small, incremental benefit.
- 25 Q. BY MR. TSAI: Okay. Along this line, here's a

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- 1 slightly different question.
- Do you agree or disagree in your opinion: The
- 3 benefit of short-term opioid therapy is supported by
- 4 multiple clinical trials?
- A. So there are reliable trials showing opioids as
- 6 effective in treatment very short term for acute pain.
- 7 But there are also studies showing that even acute
- 8 exposure can lead to significant harm.
- For example, in my report, I cite a study by
- 10 Shroeder, et al., showing that a single exposure to
- 11 opioids through a prescription from a dentist for young
- 12 people between the ages of 16 and 25, that approximately
- 13 6 percent of those individuals will go on to be diagnosed
- 14 with an opioid use disorder within that year.
- 15 My point only being, to be able to answer your
- 16 question completely, is that it's not as if the
- 17 short-term use of opioids is an entirely benign and
- 18 non-risky scenario.
- Q. Let's talk about evidence. So do you -- in your
- 20 opinion, is there enough evidence to support the use of
- 21 opioids for some people presenting with chronic
- 22 non-cancer pain?
- 23 MR. ARBITBLIT: Object to form.
- 24 THE WITNESS: No, there's -- there's not
- 25 reliable evidence to --

Q. BY MR. TSAI: I said evidence, just any

- 1 2 evidence.
- MR. ARBITBLIT: Counsel, don't interrupt her
- 4 when she's answering. Just Calm down and don't interrupt 5 her when she's answering. You can comment when she's
- 7 MR. TSAI: I just wanted to clarify.
- 8 MR. ARBITBLIT: You didn't want to clarify. You
- 9 interrupted her.
- 10 Q. BY MR. TSAI: Since you interjected, I actually
- 11 intentionally framed it broadly so I just want to point
- 12 that out.
- 13 In your opinion, is there any evidence to
- 14 support the use of opioids for some people presenting
- 15 with chronic non-cancer pain?
- 16 MR. ARBITBLIT: Object to form.
- 17 THE WITNESS: I think there is some evidence
- 18 that there is a very small benefit in some people with
- 19 the use of opioids long-term, but most of the time that
- 20 benefit does not meet a clinically meaningful threshold.
- 21 I talk about in my report, Busse does a
- 22 metaanalysis looking at the efficacy of opioids long-term
- 23 in the treatment of pain and finds that there is -- when
- 24 all of that data is put together, no clinically
- 25 meaningful difference for those individuals compared to a

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- 1 placebo and the risks incurred are obvious and great and
- 2 dose-dependent, increasing with dose duration.
- Q. BY MR. TSAI: So we've heard the term "evidence
- 4 base," and I just want to see if we can clarify that for
- 5 our jury. So let's give an example.
- What if it works, opioid therapy works for
- 7 Mrs. Smith on Long Island, and she's been taking it for
- 8 several years, and it's proven to work in her case.
- In your opinion, would that be an evidence-based
- 10 case that chronic opioid therapy works for Mrs. Smith?
- 11 MR. ARBITBLIT: Object to form.
- 12 THE WITNESS: So that's a really loaded question
- 13 because whether or not an opioid is working really
- 14 depends on who you ask. And if you ask patients
- 15 themselves, they will often endorse that it is working,
- 16 when family members will report they're not getting out
- 17 of bed, they're not engaging in family life, they
- 18 complain that their pain is worse than ever.
- 19 So that -- I think therein lies the complexity
- 20 of this, that to rely on a patient's subjective account
- 21 alone is insufficient and often wildly inaccurate.
- 22 And I think the pain community in the United
- 23 States has widely acknowledged that subject -- subjective
- 24 reports of levels of pain is insufficient to assess the 25 efficacy of opioids in the treatment of chronic pain.

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- 1 The entire field of pain in the United States
- 2 has moved toward, for example, including function as well
- 3 as reports of pain relief in that assessment.
- 4 The Kaiser Washington Post Family Foundation
- 5 survey study cites that if you ask patients themselves
- 6 with chronic pain, who are on long-term opioid therapy,
- 7 whether or not they may be developing an addiction to
- 8 that opioid, 30 percent will endorse that they're worried
- 9 about that. But when you ask their immediate family
- 10 members, 50 percent of their family members will endorse
- 11 that they're worried about that.
- 12 So there's this important gap between the
- 13 subjective experience of improvement and actual
- 14 improvement, and that is because opioids don't just work
- 15 on the new opioid receptor, they also work on the brain's
- 16 reward pathway. So they're reinforcing for reasons that
- 17 have nothing to do with pain.
- 18 Q. BY MR. TSAI: Okay. So I'm curious just to test
- 19 that. The followup question, of course, is: What if not
- 20 only Mrs. Smith herself, but also Dr. Jones, her doctor,
- 21 and her family members observed that the chronic opioid
- 22 therapy reduces her pain and does not have significant
- 23 side effects.
- 24 In your opinion, would you advise discontinuing
- 25 that course of therapy?

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- 1 MR. ARBITBLIT: Object to form. Incomplete 2 hypothetical.
- 3 THE WITNESS: I think there are rare instances
- 4 in which chronic opioid therapy for chronic pain may, in
- 5 fact, provide some small benefit. But I would argue that
- 6 even in that context, intense vigilance and monitoring is
- 7 required and a constant reassessment of the risks,
- 8 benefits and alternatives. Because at any point, that
- 9 could turn south, and what was previously beneficial may
- 10 not be.
- But I also want to add to that, that the current
- 12 standard of care and monitoring procedures are not in
- 13 existence in this country right now, largely because of
- 14 the actions of defendants that persuaded prescribers that
- 15 they didn't really need to monitor because opioids were
- 16 so safe and patients wouldn't get addicted and there are
- 17 not problems and they work great and you can go as high
- 18 as you want.
- 19 Q. So that intense vigilance and monitoring post
- 20 prescription that you advise, who does that?
- 21 MR. ARBITBLIT: Object to form.
- THE WITNESS: That vigilance and monitoring, we
- 23 are all responsible for performing a level of vigilance
- 24 and monitoring which is within our professional scope and
- 25 domain.

- 1 So that includes prescribers, that includes
 - 2 pharmacists, that includes pharmacies, that includes
 - 3 distributors, that includes opioid manufacturers.
 - 4 O. BY MR. TSAI: Includes the patients themselves?
 - 5 A. It includes patients themselves.
 - Q. It includes family members of patients?
 - A. Although -- although I would say that patients
 - 8 themselves come to us vulnerable and seeking help, and we
- 9 have a responsibility toward patients in pain, who are
- 10 incredibly vulnerable in that circumstance.
- 11 They rely on us to care for them, and that is
- 12 our responsibility. It is not their responsibility to
- $13\,$ figure out whether or not they've gotten addicted to an
- 14 opioid.
- 15 Q. So I just want to be clear. So in your opinion,
- 16 so let's say for Ms. Smith as an example. Is it your
- 17 opinion that my client, Mallinckrodt, or another
- 18 defendant should be responsible for monitoring the signs
- 19 and symptoms of her post-prescription condition?
- 20 MR. ARBITBLIT: Object to form.
- 21 THE WITNESS: On some level, yes.
- Q. BY MR. TSAI: What level?
- 23 A. Well, if you are getting reports, if -- if your
- 24 client is getting reports that individuals are being
- 25 harmed by opioids, becoming dependent, getting started

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- 1 and not being able to get off, engaging in obviously
- 2 addictive behavior, you have a responsibility to the
- 3 Public Health to do something about that.
- Or if you are aware that the distributors that
- 5 ship your pills to small communities are, in fact,
- 6 distributing large volumes to tiny little towns that
- 7 could never possibly need that many pills in a billion
- 8 years, it's your responsibility to go to your distributor
- 9 colleagues and say, you know, what's going on here.
- 10 Q. So a couple more questions about propositions I
- 11 just want to get your opinion on.
- What about this proposition: Abuse of opioids
- 13 can occur in the absence of true addiction and is
- 14 characterized by misuse for nonmedical purposes, often in
- 15 combination with other psychoactive substances?
- 16 A. I'm sorry, it's not coming up on the screen the
- 17 way you said it.
- 18 Q. I'll read the proposition again. And just tell
- 19 me if you agree or disagree in your opinion.
- Abuse of opioids can occur in the absence of
- 21 true addiction and is characterized by misuse for
- 22 nonmedical purposes, often in combination with other
- 23 psychoactive substances.
- A. I agree with that proposition.
- Q. Yeah. What about this one: Abuse and addiction

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are separate and distinct from physical dependence and
 tolerance?
 MR. ARBITBLIT: Object to form.
 THE WITNESS: I believe that the distinction
 that has been made between opioid addiction and opioid

6 dependence is primarily one of convenience for defendants

of dependence is primarily one of convenience for defendant in this case, who tried to push the use of opioids to

8 doctors and their patients by claiming that dependence in

9 and of itself is a non-risky, non-harmful condition.

10 Q. BY MR. TSAI: So let me go back to that way I 11 stated it.

12 Abuse and addiction are separate and distinct

13 from physical dependence and tolerance. In your opinion,

14 would stating that to doctors be improper?

15 MR. ARBITBLIT: Object to form.

16 THE WITNESS: I think that the division between

17 dependence and addiction that was made with the DSM-5 and

18 that is commonly taught is primarily an artificial

19 distinction to account for our iatrogenic crisis, and

20 that, in fact, the overlap between addiction and

21 dependence and the changes that occur in the brain in

22 those two conditions are characterized by significant

23 homology or similarity.

Q. BY MR. TSAI: Okay. So you think it's

25 artificial, but do you think it's misleading or

1 stems from the fact that people exposed to opioids

2 long-term develop tolerance and so invariably need a

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3 higher dose to get the same effect.

4 So I believe that the intrinsic limit has to do

5 with the damage incurred by going to higher doses.

6 Q. BY MR. TSAI: Okay. So that concept that I

7 stated, in your opinion, would stating that to doctors be

8 improper?

9 A. Yes.

10 Q. Okay. So you talked about you're not licensed

11 to practice medicine in New York, but I just wanted to

12 kind of ask the followup question: Have you ever treated

13 any person in New York? And when I say "New York," I'm

14 talking about the state and the particular counties at

15 issue in this case.

16 Have you ever treated any person in New York for

17 any medical condition related to opioids?

18 A. I sometimes have patients who see me in

19 consultation in California who come from other states. I

20 can't be -- I can't recall one having come from New York.

21 Q. Okay. And so just to be clear, throughout your

22 career, since you've been licensed in, I think 1995,

23 you've practiced in the state of California?

A. That's correct.

25 Q. Okay. Is your opinion in this case based on

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1 inaccurate?

2 MR. ARBITBLIT: Object to form.

3 THE WITNESS: I think the promotional messages,

4 the teaching messages, the marketing messages of

5 defendants in this case have been extremely misleading

6 around dependence as a separate, distinct, and in their

7 opining, non-harmful condition. Yes, I think that's been

8 a very misleading and artificial construct.

9 But now that we're there, now that we have tens

10 of millions of people who are dependent but not

11 necessarily meeting criteria for addiction because the

12 DSM-5 criteria made it very hard to diagnose addiction,

13 raising that bar, now we owe it to individuals to also

14 make this artificial distinction, to classify people as15 either meeting DSM-5 criteria for addiction or meeting

16 dependence in isolation.

But phenomenologically, what's happening in the

18 brain is probably very similar.

19 Q. Okay. Last one, I think.

20 Agree or disagree with this proposition: There

21 is no intrinsic limit to the analgesic effect of

22 hydromorphone.

23 MR. ARBITBLIT: Object to form.

24 MR. TSAI: I can spell it for you later.

25 THE WITNESS: This concept of no limit really

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1 evaluating the individual case of any specific person in

2 New York with an opioid addiction or overdose?

3 A. I don't believe so, no.

Q. Okay. So in forming your opinion in this case,

5 you did not review any individual medical record

6 identifying any specific person in New York with an

7 opioid addiction or overdose; is that correct?

8 A. That is correct.

9 Q. Okay. So, again, this is educating the jury. A

10 medical record for a patient typically contains a section

11 for that individual patient's medical history, for

12 example; is that correct?

13 A. Yes.

14 Q. Okay. So, for example, a patient's medical

15 record would have the information as to whether that

16 person had something like a previous diagnosis of a

17 substance use disorder or addiction; is that right?

A. It is well-known that the listing in the medical

19 record of diagnoses of addiction, including opioid use

20 disorder, undercount the actual cases. And the reasons

21 for that are complicated, having to do with the lack of

22 training in medical school and residency on how to

23 diagnose addiction, as well as the enormous stigma

24 associated with those diagnoses, making prescribers

25 reluctant to put it in the medical record, even when they

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- 1 know that the diagnosis is present. As well as patients
- 2 themselves being very reluctant to have that diagnosis in
- 3 the medical record, even in cases when they're getting
- 4 active treatment for opioid use disorder.
- So -- so my point -- and this is, I think, an
- 6 important one to answer your question as best I can -- is
- 7 that when it comes to opioid misuse, overuse, and
- 8 addictive use, the medical record is more often than not
- 9 woefully incomplete.
- 10 Q. So other components of a medical record would be
- 11 that doctors are trained to elicit, ask for, patients are
- 12 asked for input, provide, include family medical history;
- 13 correct?
- A. Yes. 14
- 15 Q. Include medication history; correct?
- 16 A. Yes.
- 17 Q. Include treatment and diagnosis history;
- 18 correct?
- A. Yes.
- 20 Q. Include review of systems; correct?
- 21
- 22 Q. And what does "review of systems" mean?
- 23 A. Review of systems is where you go through all
- 24 the major organ systems to see if a patient is having a
- 25 problem in another major organ system that may not be

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- 1 training and then I was in my residency. So I prescribed
- 2 whatever -- whatever other people were prescribing, but
- 3 certainly plenty of hydrocodone, oxycodone and fentanyl
- 4 products.
- Q. Okay. Do you have any basis to kind of not
- think that you prescribed -- let me just ask it direct.
- 7 Did you prescribe short-acting opioids?
- 8
- 9 Q. Did you prescribe long-acting opioids?
- 10 A. Probably.
- 11 Q. Did you prescribe both branded and generic
- 12 opioids?
- 13 A. Probably.
- 14 Q. Sitting here today, what is your best
- 15 recollection of the highest dose of an opioid that you
- 16 prescribed one of your patients?
- 17 A. I don't have a recollection of the highest dose
- 18 that I prescribed. I can tell you some of the highest
- 19 doses that I've seen in my patient population that others
- 20 are prescribing, but I don't have a recollection.
- 21 Q. I just wondered if you remembered. What
- 22 about -- I mean, you've estimated the number of patients
- 23 you've seen. Can you estimate the number of times you
- 24 have prescribed an opioid to one of your patients?
- 25 MR. ARBITBLIT: Objection.

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1

- 1 directly relevant to the reason they are presenting in
- 2 your clinic, but is certainly relevant to their overall
- 3 medical treatment.
- Q. Okay. So last time we talked, you had said, you
- 5 know, you'd been in practice since 1995, and I think you
- 6 had estimated you've seen approximately 40,000 patients
- 7 over the course of your career.
- A. (Nods head.) 8
- 9 Q. I just want to ask: Do you have any update to
- 10 that?
- 11
- 12 Q. That remains your estimate of the number of
- 13 patients that you've seen in your career?
- 14
- 15 Q. And over the course of your career, you have
- 16 prescribed many different kinds of opioids, dating back
- 17 to 1995; correct?
- 18 MR. ARBITBLIT: Object to form.
- 19 THE WITNESS: Yes.
- Q. BY MR. TSAI: All right. And you've actually
- 21 prescribed nearly every kind of opioid; is that correct,
- 22 to your patients?
- A. I don't have a distinct memory, because it was
- 24 more than 20 years ago now, of what opioids I prescribed.
- 25 But I prescribed -- I was very junior. I was in my

- Page 201 THE WITNESS: I really can't, and I continue to
- 2 prescribe opioids now, although just buprenorphine in the
- 3 treatment of opioid use disorder.
- Q. BY MR. TSAI: Okay. Well, is it safe to say
- 5 that since you've treated on the order of 40,000
- 6 patients, that the number of times you've prescribed an
- 7 opioid to one of your patients is in the thousands?
- 8 MR. ARBITBLIT: Object to form.
- 9 THE WITNESS: I think that's probably fair.
- 10 Q. BY MR. TSAI: And to the best of your
- 11 recollection, did you ever prescribe opioids to your
- 12 patients in combination with other drugs, in situations
- 13 where they were taking other drugs?
- A. On the inpatient setting, there's hardly a
- 15 patient who's just on one drug, so yes.
- Q. I'd like those agree or disagree. So I'm going
- 17 to go back to some more, but it's a different topic.
- 18 So agree or disagree in your opinion: In terms
- 19 of the treatment of pain, using pain medicine, each
- 20 individual's medication regimen should be personalized?
- 21 MR. ARBITBLIT: Object to form.

24 disagree on without specifics.

- 22 THE WITNESS: So, to me, that is a broad,
- 23 sweeping question that I would be reluctant to agree or
- 25 Q. BY MR. TSAI: So that affirmative statement "in

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- 1 the treatment of pain using pain medication, each
- 2 individual's medication regimen should be personalized,"
- 3 you're not -- you're not comfortable agreeing with that?
- 4 MR. ARBITBLIT: Object to form.
- THE WITNESS: I -- I agree that medical
- 6 treatment should be personalized, but also needs to be
- 7 considered in the broader context of a Public Health
- Q. BY MR. TSAI: And in designing a medication
- 10 régime, personalizing it for a patient, whose -- who does
- 12 MR ARBITBLIT: Object to form.
- 13 THE WITNESS: Well, that's a great question
- 14 because in the past 30 years, it's mainly been your
- 15 client who has designed that. The work of the defendants
- 16 has been such a force in the way that pain is treated,
- 17 from the Joint Commission to the Federation of the State
- 18 Medical Boards to CME, that that protocol is largely the
- 19 invention of defendants in this case.
- Q. BY MR. TSAI: Here's another statement. Agree
- 21 or disagree, in your opinion: Opioids vary greatly in
- 22 their pharmacokinetic and pharmacodynamic profiles, which 22 her best judgment, but that judgment needs to be informed
- 23 in turn are influenced by route of administration and
- 24 individual tolerability.

1

25 MR. ARBITBLIT: Object to form.

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- 1 medical profession. We need much more robust training, 2 and we need many more resources to create the kind of
- 3 medical infrastructure to make sure that safe prescribing
- 4 is happening and that benefits actually are outweighing
- 5 the risks and helping people who have become physically 6 dependent get off.
- Q. Right. And so putting aside your view of the
- 8 state of medical training in the United States, in terms
- 9 of roles, do you agree that it is the role of the
- 10 prescribing physician to weigh the risks and benefits of
- 11 any pain medication when treating their individual
- 12 patient?
- 13 MR. ARBITBLIT: Object to form.
- 14 THE WITNESS: Healthcare providers, physicians,
- 15 nurse practitioners, other healthcare providers are not
- 16 working in a vacuum. They have enormous pressures on
- 17 them to practice according to protocols and algorithms
- 18 implemented by a healthcare facility. There are other
- 19 pressures that I've talked about in terms of patient
- 20 satisfaction surveys, et cetera.
- 21 So, yes, a physician needs to exercise his or
- 23 by the evidence, and it must be taken into account that
- 24 there are other pressures on physicians when it comes to
- 25 which medicine they choose to prescribe.

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1

- THE WITNESS: Opioids are similar and different
- 2 in many ways. So there is variation between opioids in
- 3 the pharmacokinetics and pharmacodynamics, depending upon
- 4 the route of delivery. But there are universal themes
- 5 for all opioids, including the way that they bind and 6 stimulate the opioid receptor, as well as the way that
- 7 they're rewarding in the dopamine reward pathway,
- 8 contributing to their addictive potential.
- Q. BY MR. TSAI: Okay. But ultimately, how about
- 10 this statement: Comparing dosages across opioids and
- 11 individuals is challenging.
- 12 A. Yes, I agree.
- Q. Okay. How about this one: Physicians should
- 14 individualize therapy based on a review of the patient's
- 15 potential risks, benefits, side effects and functional
- 16 assessments and monitor ongoing therapy accordingly.
- 17 MR. ARBITBLIT: Object to form.
- 18 THE WITNESS: I would qualify that by saying
- 19 that statement is true, but only when informed by a good
- 20 understanding of the evidence.
- 21 Q. BY MR. TSAI: Okay.
- A. For the benefit and risk of opioids. And only
- 23 when that monitoring is done at an appropriate level of
- 24 vigilance to really be able to detect the harm.
- 25 And right now, we're not there in terms of the

- Page 205 So it's not always in their autonomous control.
- 2 Q. BY MR. TSAI: Okay. Do you agree with this
- 3 statement: Without more -- without detailed data
- 4 describing the clinical context, in particular the
- 5 severity of pain, it's difficult to accurately determine
- 6 medical appropriateness with respect to a prescription
- 7 for any given patient?
- 8 MR. ARBITBLIT: Object to form.
- 9 THE WITNESS: I disagree with that statement.
- 10 Q. BY MR. TSAI: Okay. Well, can we agree that
- 11 physicians in New York appropriately prescribed opioids
- 12 in at least some circumstances?
- 13 A. That's a big blanket statement that I would be
- 14 reluctant to agree to.
- 15 Q. Is it your opinion that all doctors throughout
- 16 the state of New York who wrote prescriptions for opioid
- 17 medicines for their patients did so inappropriately?
- 18 A. The vast majority, yes.
- 19 Q. Okay. The vast majority is different from all.
- 20 A. Uh-huh.
- 21 Q. Can you quantify it?
- 22 A. There may be some rare instances in which opioid
- 23 prescribing was appropriate, but in the vast majority, I
- 24 and my medical colleagues across the country, including

25 the state of New York, have been describing opioids at

52 (Pages 202 - 205)

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1 way too high doses for way too long.

- Q. Well, we're going to be spending a lot of time
- 3 at trial, including the jury. So can you put a number on
- 4 that?
- 5 MR. ARBITBLIT: Object to form.
- 6 Q. BY MR. TSAI: What, in your opinion, the
- 7 percentage of prescriptions by doctors in New York to
- 8 their patients that, in your opinion, were medically
- 9 inappropriate?
- 10 MR. ARBITBLIT: Object to form.
- 11 THE WITNESS: I have seen in my clinical
- 12 experience no cases of opioids at high doses for long
- 13 duration in which the benefits outweighed the risks, and
- 14 I've seen a lot of patients in my career.
- 15 Q. BY MR. TSAI: Yeah. So your answer, I just
- 16 heard, is your practice, and that's in California. This
- 17 case is in New York.
- So just to be clear: Is your opinion in this
- 19 case based on reviewing any document enabling you to
- 20 identify a single actual doctor who prescribed a single
- 21 actual opioid pill to a single actual individual in
- 22 New York?
- 23 MR. ARBITBLIT: Object to form. Objection to
- 24 the prologue.
- 25 THE WITNESS: I am aware of lay press reports of

- 1 unnecessary or inappropriate?
 - 2 A. My opinion is not based on specific
 - 3 prescriptions. It's based on aggregate prescriptions.
 - 4 Q. Okay. Have you, in your practice, prescribed
 - 5 any medically inappropriate prescriptions of opioids to

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- 6 any of your patients?
- A. Can you define "medically inappropriate"?
- 8 Q. I'd like to hear your definition.
- 9 A. Well, I think there are a couple ways to think
- 10 about how to define that. Medically inappropriate might
- 11 be a scenario in which I know it's not the right
- 12 prescription for my patient and I prescribe it anyway.
- 13 And I have never engaged in that kind of practice.
- 14 But another form of medical inappropriateness is
- 15 where I believe that it's the appropriate prevention, but
- 16 I'm wrong. But based on my belief, I prescribe the 17 prescription -- I prescribe that medication for my
- 18 patient. I have engaged in that kind of error in my --
- 19 in my career, yes.
- Q. So taking that definition, using that one.
- A. The latter one?
- Q. The latter one, yes. How many times have you
- 23 prescribed a medically inappropriate prescription of an
- 24 opioid to your patients?
- 25 A. Well, as I testified previously, in the late

- 1 single individual doctors who prescribed single actual
- 2 opioid pills to single actual individuals in New York,
- 3 who were engaging in egregious overprescribing.
- 4 Q. BY MR. TSAI: So these are reports in the
- 5 newspaper about pill mill doctors in New York?
- 6 A. That's right.
- 7 Q. Okay. Other than that, can you give -- identify
- 8 any doctor who prescribed opioid medications to any
- 9 individuals in New York?
- 10 A. No.
- 11 Q. Okay. Did you, in forming your opinion, ask for
- 12 information from the New York counties or from the New
- 13 York State regarding prescriptions that they determined
- 14 were medically improper?
- 15 A. Well, I have reviewed data on New York
- 16 prescribing, and it is here in my report. I refer you to
- 17 page --
- 18 Q. Yeah, I think I know what you're -- it's the
- 19 Nassau County data prescribing data that you referenced.
- A. That's correct.
- Q. Okay. So my question was a bit different.
- So just let me ask this: Is your opinion in
- 23 this case based on identifying concrete examples of
- 24 specific prescriptions of any opioids written in New York
- 25 that you believe, in your opinion, were medically

- Page 209 1 1990s -- well, throughout the 1990s in my medical school
- 2 and residency training, I was engaging in inappropriate
- 3 opioid prescribing on a regular if not daily basis.
- 4 Because I was prescribing in a way that was informed by
- 5 the misleading promotional messages of defendants, and
- 6 the entire healthcare system at that point was hijacked
- 7 by Pharma.
- 8 Once I became a psychiatrist, opioid prescribing
- 9 was out of my scope of practice, although pain treatment
- 10 was not. And then as I became more knowledgeable and
- 11 more invested in helping patients who had become
- 12 dependent or addicted to opioids, patients struggling
- 13 with chronic pain, and I began to research this area, I
- 14 got a courtesy faculty appointment in Stanford Department
- 15 of Pain Medicine, began to see patients in their clinics,
- 16 and then got the x-waiver certification to prescribe
- 17 buprenorphine for opioid addiction, then I resumed opioid
- 18 prescribing.
- 19 And in that context, I have made errors in
- 20 opioid prescribing, but I like to think those errors have
- 21 been few.
- 22 Q. Umm --
- A. So well-intentioned errors, prescribing. An
- 24 example might be thinking that a patient could steward a
- 25 seven-day supply of buprenorphine and discovering by

Page 210
1 urine drug screen or prescription drug monitoring

- 2 database seven days later that no, in fact, they could
- 3 not.
- 4 Q. Okay. So let's talk about that example. So
- 5 that's an example of diversion; right?
- 6 A. Not necessarily. So diversion means that -- as
- 7 you know -- just clarifying for the jury -- that the
- 8 pills make it to someone other than for whom they were
- 9 intended. But a very common problem that can arise is
- 10 that patients misuse their own opioid prescription.
- 11 So most of the time in my clinical population,
- 12 it's their personal misuse of the prescription rather
- 13 than diversion, per se.
- 14 Because I can tell you most patients don't admit
- 15 to diversion unless it's been years in the past. I
- 16 have -- I have had patients tell me about their diversion
- 17 activities, but usually not when they're under my care
- 18 and not with my prescription. They don't do that.
- 19 They'll in -- in the process of recovery, talk
- 20 about prescriptions they received from another provider
- 21 in the past and diverted, which has been a good education
- 22 for me about diversion.

A. Yes, we can agree.

4 someone to become addicted?

11 opioid; is that right?

A. Yes, we can agree to that.

- Q. Well, can we agree that not every single opioid
- 24 medicine that one of the defendants made was diverted to

Q. Can we agree that not every single opioid

7 instances in your practice where you realized that your

A. Well, I want to qualify that answer. I think I

16 cases that diversion was occurring and made adjustments

13 would sharpen the accuracy of my response on that to

14 say -- and I did try to do this a little bit earlier in

15 the deposition -- that I have suspected in some rare

17 accordingly, but it is not my clinical experience that

19 becomes an obvious situation for involving, you know,

20 criminal justice, and that most of my knowledge from

21 patients about the diversion activities is diversion that

22 they have engaged in in the distant past, after they're

25 would get a tox screen that was inconsistent with

Q. So these suspicious cases, for example, you

18 patients will openly admit to diversion such that it

8 patients were giving away the opioid that you had

9 prescribed them to, you know, third parties, like

10 friends, family, to whom you did not prescribe the

Q. Okay. So you talked previously about examples,

3 medicine that the defendant businesses made caused

25 an illegal use?

1

12

- 1 properly using what you had prescribed; is that --
 - 2 A. Yes.
 - Q. Okay. So in -- and can you give a number as to
 - 4 how many suspicious cases you -- over the course of your

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- 5 career, that you've encountered in this way?
- A. I really can't give a number based on my
- 7 personal experience. I don't tend to count like that,
- 8 and I wouldn't want to give you a number that was
- 9 inaccurate.
- 10 Q. Well, could we say more than ten?
- 11 MR. ARBITBLIT: Object to form.
- 12 THE WITNESS: More than ten individual cases of
- 13 diversion?
- 14 Q. BY MR. TSAI: Where you suspected diversion in
- 15 your patients?
- 16 A. We could probably say more than ten, yes.
- 17 Q. More than a hundred?
- 18 A. No, I wouldn't say more than a hundred.
- 19 Q. Okay. So when you had -- you suspected
- 20 diversion, how did you -- tell me how you acted to
- 21 counteract that suspicion, to counteract what you believe
- 22 was diversion?
- A. So I also want to qualify my prior statement
- 24 regarding your attempts to quantify my patient experience
- 25 around diversion.

Page 211

1 Diversion is not something that I v

- Diversion is not something that I was even aware of or looked for or was trained to look for in medical
- 3 school or residency. So in the '90s and early -- in the
- 4 '90s, when I was prescribing opioids as part of my role
- 5 as a resident or a physician in training, I didn't even
- 6 know what diversion meant. Didn't have the first concept
- 7 about it.
- 8 It's really only since I've become an addiction
- 9 medicine specialist and I'm now running a clinic that I
- 10 appreciate what diversion is and have a checks and
- 11 balances in place to monitor, to the best of my ability,
- 12 what diversion is all about. And I attribute that to the
- 13 lack of proper training that I got in this regard.
- So, sorry, I just wanted to qualify that.
- Q. So among the checks and balances, for example,
- 16 did you cut off the -- stop the prescription to that
- stop the prescription to that
- 17 particular patient? I just want to know what you do.
- 18 A. Yeah. So it depends on the individual patient.
- 19 And again, these aren't obvious cases of diversion where
- 20 these -- you know, these aren't like people who are
- 21 running a drug business. This is most often -- or I
- 22 would say all of my patients who I am aware of may have
- 23 engaged in some level of diversion, I had a suspicion for
- 24 it. It was not confirmed.
- 25 But the first order of business is to discuss

54 (Pages 210 - 213)

23 already in recovery.

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1 with the patient that I'm concerned about diversion or

- 2 misuse, to ask them whether or not they can verify that
- 3 that behavior is happening.
- Patients will typically -- will often admit to a
- 5 misuse problem. Will not typically admit to a diversion 6 problem.
- 7 And then what I will typically do is talk about
- 8 alternative treatment strategies. You know, this is not
- 9 working for you. We need to think of a higher level of
- 10 care or another intervention of some sort. And there are
- 11 myriad treatments for opioid addiction.
- 12 So I will then begin to steer them in that
- 13 direction.
- 14 Q. Okay. So in any of these, say, double-digit
- 15 instances where you suspected diversion, did you need
- 16 Mallinckrodt or any defendant to detect and counteract
- 17 that diversion for your patient?
- 18 MR. ARBITBLIT: Object to form.
- 19 THE WITNESS: I mean, Mallinckrodt is the reason
- 20 that, you know, the opioid epidemic, this problem is on
- 21 my doorstep in the first place. Without Mallinckrodt, I
- 22 probably wouldn't be an addiction specialist.
- Q. BY MR. TSAI: I'm talking about your checks and
- 24 balances for your patients. Did you call Mallinckrodt

MR. ARBITBLIT: Object to form.

Q. BY MR. TSAI: To take that action?

MR. ARBITBLIT: Object to form.

THE WITNESS: That would be great if

5 to take an action to check and balance that?

Q. To detect the addiction of your patient and then

25 and did you need them to do that?

A. To take what action?

- 2 were talking about, so let's take the example of one of

Q. BY MR. TSAI: So let's take -- take up where we

Page 216

Page 217

- 3 your actual patients, you had a suspicion that he or she
- 4 was diverting the opioids that you had prescribed. For
- 5 example, you did a urine tox screen, it wasn't consistent
- 6 with his taking the regimen.
- In any of those instances where you suspected
- 8 diversion, did you report that to the police or any
- 9 other -- any other authority?
- 10 MR. ARBITBLIT: Object to form.
- 11 THE WITNESS: So the suspicion for diversion
- 12 when a urine drug screen is negative must be included in
- 13 the differential diagnosis for that negative drug screen
- 14 in a patient who's being prescribed an opioid. But it's
- 15 not the only thing that may be going on.
- 16 As I said before, it could be an honest error.
- 17 It could be an inaccuracy in the drug test itself,
- 18 necessitating confirmatory testing in some cases. It
- 19 could be even misuse on the part of that individual, for
- 20 example, taking more of the drug than prescribed and then
- 21 running out early, and hence not having any drug in their
- 22 system at the time.
- 23 So I have never been in a situation where my
- 24 threshold of suspicion regarding diversion was enough to
- 25 motivate me to involve anybody else except for the

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- 1 patient and their immediate team, in some instances,
- 2 including family members, and also to prompt me to change
- 3 my care of that individual.
- Q. BY MR. TSAI: Okay.
- 5 A. So I always do something.
- 7 A. But I have never been in a situation where
- 8 the -- the -- I was so convinced that diversion was
- 9 occurring that I then felt it needed to be reported to an
- 10 beyond the scope of what might be reasonable for somebody 10 outside entity.

8 Mallinckrodt wanted to get involved in creating an

9 infrastructure to help with that. I think that isn't

- 11 who manufactures opioids.
- 12 Q. BY MR. TSAI: I'm saying in your history, you
- 13 had this practice, you had these patients --
- 14

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- 15 Q. -- was Mallinckrodt involved, any defendant?
- 16 MR. ARBITBLIT: Object to form.
- 17 THE WITNESS: Not directly involved, but
- 18 indirectly involved in the way I described.
- 19 MR. ARBITBLIT: Let's take a break.
- 20 MR. TSAI: Okay.
- THE VIDEOGRAPHER: Going off the record, the
- 22 time is 2:31 p.m.
- 23 (Recess.)
- 24 THE VIDEOGRAPHER: Back on the record, the time 24 as usual. I don't do that.
- 25 is 2:48 p.m.

- 11 Q. Okay. So in other words, the suspicion of
- 12 illegal diversion could be a false positive?
- 13 A. That is true.
- Q. All right. It is not easy to ascertain whether
- 15 a suspicion of diversion, in fact, equals actual illegal
- 16 activity. Agree?
- 17 MR. ARBITBLIT: Object to form. Object to form.
- 18 THE WITNESS: You'll note that I said that even
- 19 in the absence of knowing for sure whether diversion is
- 20 taking place, I assume on some level that it could be and
- 21 I take action in response. And that's very important
- 22 piece, that I don't say, oh, well, it might be happening, 23 but I'm not sure so I'm just going to continue business
- 25 Q. BY MR. TSAI: So in that example, at the ground

Page 218 1 level when you had a suspicion of diversion, Mallinckrodt 1 adverse consequences due to prescription opioids that 2 or any of the defendant business -- businesses, they 2 they should have and could have acted on, but they did 3 wouldn't have known about that situation because you 3 not act on, and that they, in fact, are better equipped 4 didn't report it out. 4 to do that than I, an individual practitioner, who is Do you agree? 5 only seeing this isolated instance of this one patient MR. ARBITBLIT: Object to form. 6 and may not have an aggregate sense of what's happening 6 7 Q. BY MR. TSAI: That particular instance of 7 in the community. Q. BY MR. TSAI: Well, the population, whether it's 8 suspected diversion? MR. ARBITBLIT: Object to form. 9 five or ten or a hundred, is made up of individuals; 10 THE WITNESS: Mallinckrodt would not have known 10 right? 11 about that suspected diversion necessarily unless that 11 MR. ARBITBLIT: Object to form. 12 diversion was happening at such a high rate among so many 12 THE WITNESS: (Nods head.) 13 providers that it was contributing to a serious Public 13 Q. BY MR. TSAI: Okay. So is that a "yes"? 14 Health problem in my community, at which point the death 14 A. A population is made up of individuals. 15 15 and addiction statistics should be sufficient to alert Q. Okay. So can you explain to me in this example, 16 Mallinckrodt that a diversion problem is taking place. 16 how you believe any defendant could have or should have 17 Q. BY MR. TSAI: So in that instance -- let's talk 17 known about this instance of diversion? 18 about this example of your actual patient -- you agree 18 MR. ARBITBLIT: Objection. Asked and answered 19 badgering, redundant. 19 you were in a better position compared to a Mallinckrodt 20 or any of the other defendant businesses here to detect 20 THE WITNESS: Yeah, I feel like I -- I answered 21 that instance of diversion? 21 the question at the level that it needed to be answered. 22 Q. BY MR. TSAI: Okay. What about for this MR. ARBITBLIT: Object to form. 22 23 THE WITNESS: I think you could make the 23 individual? 24 opposite argument, that, in fact, Mallinckrodt, which has 24 MR. ARBITBLIT: Object to form. 25 access to the ARCOS database that I, an individual 25 O. BY MR. TSAI: Because that's the level I think Page 219 1 front-line clinician don't have access to and don't know 1 it needs to be answered. 2 A. Uh-huh. 2 about, would be in a better position to detect population 3 Q. Okay? 3 level diversion than I as an individual practitioner 4 might be. 4 A. Yes. Q. BY MR. TSAI: I didn't ask about population. 5 MR. ARBITBLIT: Object to form. 6 I'm saying Bob Chen, your patient who had failed his tox THE WITNESS: But it's a hypothetical situation. 7 screen, and you didn't report that out to anyone, how 7 First it was Mr. Smith and then it was Mr. Chen. 8 would Mallinckrodt, in that example, know that there was Q. BY MR. TSAI: Yeah. And the order from this 9 Court is that assumptions based on facts -- your 9 diversion going on? 10 MR. ARBITBLIT: Objection. Form. 10 Interrogatory, that's when we asked you to assume is 11 Q. BY MR. TSAI: Can you explain? 11 true -- you have to answer. So let's focus on that. 12 A. I think I did explain. I think I gave an answer 12 I assume that Mr. Chen, your patient, failed his 13 urine tox test. You did not report it out to anyone. 13 to that. 14 Q. No, that example, that they know in that. 14 You suspected that he was criminally diverting it by 15 15 selling it, giving it to people who -- who shouldn't have Your opinion -- you're telling the jury you 16 believe Mallinckrodt should have known that Bob Chen 16 gotten it. 17 17 failed his tox test even though you didn't report it out Explain to me in that concrete example, given 18 to anyone. I just want to see if that's your opinion. 18 that hypothetical you have to assume is true, how any of 19 MR. ARBITBLIT: Object to form. 19 the defendant businesses would be able to detect that 20 THE WITNESS: My opinion is broader than what 20 diversion? 21 you're trying to get me to agree to, and that's why I'm 21 MR. ARBITBLIT: Objection. Incomplete 22 not willing to agree to it. 22 hypothetical.

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THE WITNESS: Again, I feel like I answered it.

24 Although the defendants may not have been aware of that 25 individual isolated case of mine -- I concede that to

23

My opinion is that Mallinckrodt and other

24 defendants had access to population-level data that could

25 have informed -- that did inform their knowledge of

23

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- 1 you -- they had been aware on an aggregate level of the
- 2 harm due to the oversupply of opioids, including the
- 3 problem of diversion, and yet they did nothing about it.
- 4 Q. BY MR. TSAI: So let's go back to the agree or
- 5 disagree. I have some other propositions.
- 6 Agree or disagree in your opinion: Patients for
- 7 whom chronic opioid therapy are being considered should
- 8 be screened for risks and contraindications.
- 9 A. There is no evidence that screening patients
- 10 prior to initiating opioid therapy reduces their risk of
- 11 developing an opioid use problem. We do not have good
- 12 screening tools. So hypothetically, it makes sense, if
- 13 we could parse out those 30 percent of individuals who's
- 14 going to develop an opioid use problem from the rest,
- 15 that would be great, but we don't have the tools to do
- 16 that.
- 17 And in educating physicians that screening
- 18 actually worked, that was another form of misrepresenting
- 19 the evidence.
- 20 Q. So just to be clear, in your opinion, would
- 21 stating that proposition to practitioners, "patients for
- 22 whom chronic opioid therapy is being considered should be
- 23 screened for risks and contraindications," be misleading?
- A. I think it's -- I think it's misleading because
- 25 it's incomplete.

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- 1 Q. How about this one: Before initiating chronic
- 2 opioid therapy, physicians should take adequate time to
- 3 inform patients in simple language of the associated
- 4 risks?
- 5 A. Yes, I agree with that.
- 6 O. Okav.
- 7 A. Assuming that that physician is properly
- 8 educated on what those risks are.
- 9 Q. Okay. How about this one: Patient education
- 10 can help curb opioid misuse and reduce the risk of
- 11 developing opioid use disorder?
- 12 MR. ARBITBLIT: Object to form.
- 13 THE WITNESS: I don't think that we don't have
- 14 good data to show whether or not educating patients will
- 15 actually curb their risk of opioid misuse. I think it's
- 16 a logical assumption, but it's not actually been proven
- 17 to be the case, and I can tell you that the way that
- 18 opioids working on the brain is that they are reenforcing
- 19 beyond what the patient may understand about their risks.
- 20 So it's a logical proposition, but I don't
- 21 believe there's evidence to actually show that educating
- 22 patients about the risks reduces their chances of
- 23 developing opioid use problem.
- Q. BY MR. TSAI: Okay. So then just to be clear:
- 25 Do you believe stating that proposition would be

1 misleading to practitioners?

- 2 A. Yeah, I think that would be misleading.
- Q. What about this one: Physicians should also
- 4 perform ongoing risk-benefit assessments throughout the
- 5 course of therapy because problems can arise at any
- 7 A. Yes, I would agree with that.
- 8 Q. Okay. How about this one: Patients should be
- 9 reevaluated at least every three months, even when stable
- 10 and doing well, and more frequently if problems arise?
- 11 A. Yes, I agree with that.
- 12 O. Okay. How about this: The risk for opioid
- 13 abuse is increased in patients with a personal or family
- 14 history of substance abuse, including drug or alcohol
- 15 abuse or addiction, or mental illness, for example, major
- 16 depression?
- 17 A. Yes, I agree with that.
- 18 Q. Okay. Agree or disagree in your opinion with
- 19 this proposition: Patients at increased risk may still
- 20 be appropriately treated with modified-release opioid
- 21 formulations, however, these patients will require
- 22 intensive monitoring for signs of misuse, abuse or
- 23 addiction?
- 24 MR. ARBITBLIT: Objection.
- 25 THE WITNESS: Can you restate just because the

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- 1 transcription is not accurately represented. It says
- 2 "real estate" opioid formulation. So would you repeat?
- 3 Q. BY MR. TSAI: Okay. What about this
- 4 proposition: Patients at increased risk may still be
- 5 appropriately treated with opioid medications; however,
- 6 these patients will require intensive monitoring for
- 7 signs of misuse, abuse or addiction?
- 8 MR. ARBITBLIT: Object to form.
- 9 THE WITNESS: I think it's really important to
- 10 qualify whether we're talking about short-term opioid
- 11 therapy or long-term opioid therapy because the risks
- Therapy of long-term opioid therapy because the risk
- 12 really diverge there.
- 13 I do agree that even patients with addiction may
- 14 at times need a short-term course of opioid therapy for
- 15 pain and that those individuals are at increased risk.
- 16 But it's also true that per Edlund, the risk of
- 17 developing opioid use problem -- the greatest risk factor
- 18 is actually dose and duration of the opioid -- the higher
- 19 the dose, the longer the patient's on it, and that that
- 20 risk outweighs any personal or family history of an
- 21 opioid use problem.
- Q. BY MR. TSAI: So let's specifically substitute
- 23 in an extended-release opioid medication. If we put that
- 24 in, patients at increased risk may still be appropriately
- 25 treated with an extended-release opioid formulation,

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1 would you agree or disagree with that?

- 2 A. Can you say the whole proposition again?
- 3 Q. Yeah.
- Patients at an increased risk may still be
- 5 appropriately treated with extended-release opioid
- 6 formulations; however, these patients will require
- 7 intensive monitoring for signs of misuse, abuse or
- 8 addiction?
- 9 MR. ARBITBLIT: Object to form.
- 10 THE WITNESS: I think there would -- and when
- 11 you say extended release, you mean short-term, long-term
- 12 opioid therapy. I'll object because --
- 13 (Interruption in proceedings.)
- 14 MR. TSAI: Someone's -- I think someone's not on
- 15 mute. We can hear you.
- 16 THE WITNESS: Yeah. So in general, I don't
- 17 agree.

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16 refills.

- 18 (Interruption in proceedings.)
- 19 THE WITNESS: So I don't believe that opioid
- 20 long-term opioid therapy is --
- 21 (Interruption in proceedings.)
- 22 THE REPORTER: Can we go off the record?
- 23 THE VIDEOGRAPHER: Going off the record, the

Q. BY MR. TSAI: Okay. Do you agree that risk

Q. Okay. Is one of those risk factors for opioid

8 addiction a personal history of a substance use disorder?

Q. Okay. Same question for family history of a

Q. Same question for a history of doctor shopping.

Q. Same question for a history of seeking early

18 is highly correlated with prescription opioid misuse, and

19 prescription opioid misuse is highly correlated,

20 predictive of developing an opioid use disorder. So,

21 yes. Whether it's a causative or a risk factor, but yes.

23 sexual abuse is also a risk factor for opioid addiction.

25 many medical conditions, including mental health

A. So in general, doctor shopping and early refills

O. Okay. Same question: Preadolescent history of

A. Childhood trauma in general is a risk factor for

4 factors for opioid addiction other than mere exposure

24 time is 3:02 p.m.

2 is 3:03 p.m.

A. Yes.

11 substance use disorder.

A. Correct.

5 exist?

25 (Discussion off the record.)

- 1 conditions, including addiction, yes.
 - 2 Q. And psychiatric comorbidities is also a risk

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- 3 factor.
- 4 A. Yes.
- 5 Q. That's a big term, big mouthful. Can you
- 6 explain to the jury what that means?
- A. That means an individual who has a psychiatric
- 8 disorder other than the disease of addiction. So that
- 9 would include everything from major depression to
- 10 obsessive compulsive order to bipolar disorder to
- 11 schizophrenia.
- 12 O. Okay. So given all these risk factors, do you
- 13 agree that healthcare providers should assess each
- 14 individual for opioid risk based on specific factors?
- 15 MR. ARBITBLIT: Object to form.
- 16 THE WITNESS: Healthcare providers should assess
- 17 risk factors for opioid addiction informed by the
- 18 knowledge that patients who screen positive for those
- 19 risk factors are not the only patients who are at risk
- 20 for developing opioid use problems, and that, in fact,
- 21 our screening tools are not effective at predicting who
- 22 will and will not develop an opioid use disorder.
- 23 So although we have no predictive tools, I
- 24 nonetheless do endorse screening for those risk factors
- 25 as part of a complete medical exam.

- THE VIDEOGRAPHER: Back on the record, the time 1 Q. BY MR. TSAI: Okay. So can we agree that all 2 things being equal, a person with either active or a
 - 3 history of substance use disorders is a higher risk

 - 4 candidate for opioid therapy than a person with no past
 - 5 or current history of substance use disorders?
 - A. I'm not sure we actually can agree to that
 - 7 because although we can look at large populations and see
 - 8 who has an opioid use disorder and see who has those risk
 - 9 factors and note higher prevalence of those risk factors
 - 10 in patients who develop an opioid use disorder, we still

 - 11 do not as of yet have a clinical predictive tool that
 - 12 will allow us to screen for anything in order to be able
 - 13 to separate who will and will not develop an opioid use
 - 14 disorder.
 - 15 The bottom line importantly being that even
 - 16 patients with none of those risk factors can develop an
 - 17 opioid use disorder, period.
 - 18 Q. How about this: Patients who are prescribed
 - 19 opioids are not all at equal risk for developing opioid 20 addiction?
 - 21 A. Patients who are on higher doses for longer
 - 22 duration are at increased risk of developing opioid risk
 - 23 disorder. Patients who have some of the risk factors
 - 24 you've mentioned, like co-occurring psychiatric
 - 25 disorders, are at increased risk of developing opioid use

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- 1 disorder, but the relative risk of dose and duration
- 2 outweigh the risks of those other -- those other risk
- 3 factors.
- Q. And the dose of an opioid medication for a
- 5 particular patient can change over time. Agreed?
- 6 A. In fact, it typically does change over time as
- 7 patients develop tolerance, given the way that we've been
- 8 practicing, to respond to tolerance by increasing the
- 9 dose, given the way that we have been miseducated to
- 10 believe that quote/unquote no dose is too high.
- 11 Q. And it's the doctor who decides what dose of an
- 12 opioid medication his or her individual patient receives,
- 13 when prescribed, and over the course of treatment.
- Do you agree?
- 15 MR. ARBITBLIT: Object to form.
- 16 THE WITNESS: Yes and no.
- 17 Q. BY MR. TSAI: Who else decides -- who else
- 18 decides the dosage regimen of a particular doctor's
- 19 particular patient?
- 20 A. So the amount and duration and choice of the
- 21 opioid is heavily influenced by things like what's on the
- 22 pharmacy formulary for a given hospital or what that
- 23 patient's insurance will cover or whether or not the
- 24 Joint Commission infiltrated that hospital and said you'd
- 25 better, in so many words, prescribe opioids to any

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- 1 patient that endorses pain above a given level.
- 2 Or in a situation where a patient has demanded a
- 3 certain opioid prescription and rated that -- that doctor
- 4 poorly because of it or in a situation where that
- 5 patient -- that doctor may be afraid that they will get
- 6 sued or lose their medical license if they don't do
- 7 everything in their power, i.e., prescribe an opioid to
- 8 treat that patient's pain.
- 9 So lots of invisible forces inside of medicine
- 10 driving prescribing, which the defendants in this case
- 11 well understood and exploited in order to promote their
- 12 products.
- Q. Let me ask you this, and this is a hypothetical:
- 14 So let's assume the same dose and duration for Mrs. Smith
- 15 and Mr. Chen, same dose and duration. Mrs. Smith has
- 16 never been depressed, never taken drugs before, never had
- 17 a family member who took drugs, has a high-paying job,
- 18 and then took an opioid medication for a legitimate pain
- 19 condition.
- In your opinion, would Mrs. Smith have the same
- 21 risk of addiction as someone, call him Mr. Chen, with a
- 22 long history of severe depression, history of prior
- 23 illicit drug use, family history of drug use, unemployed,
- 24 and who was doctor shopping?
- MR. ARBITBLIT: Object to form.

- THE WITNESS: So you've asked me a hypothetical
- 2 so I'm going to answer by talking about how I practice.
- 3 Because we're not talking about a specific patient.
- 4 And the way that I practice, which I think is
- 5 informed by the evidence and many years of clinical
- 6 experience, is that any patient, regardless of those --
- 7 having or not having those risk factors, is at risk for
- 8 developing an opioid use problem. And so I treat all of
- 9 my patients the same in that regard, with the same level
- 10 of caution and the same level of monitoring and
- 11 vigilance.
- 12 Q. BY MR. TSAI: And you say "at risk." My
- 13 question is in that scenario, comparing those two
- 14 individual patient cases, is it your opinion that they
- 15 have the same risk, different risk? What is that? What
- 16 is your opinion on that? Not at risk, but the degree of
- 17 risk.
- 18 A. So when we're talking about clinical care and
- 19 I'm sitting in my office dealing with real, live
- 20 patients, I fully acknowledge that I have no crystal ball
- 21 for being able to determine who will and will not develop
- 22 an opioid use problem.
- I have seen many patients like your hypothetical
- 24 Mrs. Smith, high functioning, well educated, high-paying
- 25 job, no core current mental illness, no history of

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- 1 substance use problems, who goes on to very quickly
- 2 develop an opioid use disorder in the context of
- 3 receiving a prescription from a doctor.
- 4 Likewise, I have seen patients like your
- 5 hypothetical Mr. Chen -- depressed, unemployed, doctor
- 6 shopping -- who doesn't develop an opioid addiction.
- 7 So when we're talking about the level of
- 8 clinical care -- not population-level studies, but
- 9 clinical care and my ability to prognosticate, I assume I
- 10 have zero ability to do that.
- 11 Q. Okay. So that -- now you kind of reversed.
- 12 First you were in population mode and --
- 13 A. Yep.
- MR. ARBITBLIT: Ask a question, Counsel. Don't
- 15 lecture.
- 16 Q. BY MR. TSAI: So let's talk about population
- 17 level.
- MR. ARBITBLIT: Don't lecture the witness,
- 19 Counsel. Ask a question.
- Q. MR. TSAI: Do you have an opinion as to the
- 21 relative degree of risk on a population level, given that
- 22 scenario?
- A. So I cite Edlund in my report. On page 20.
- Q. So we're on the same page --
- 25 A. Yeah.

Page 234 Page 236 1 Q. -- in terms of interpreting reading Edlund, you 1 information on how average daily dose and duration of 2 agree that Edlund was a -- was a study about 2 opioid therapy may supply likelihood of development of an 3 associations, not --3 incident of opioid use disorder is limited, do you have A. Uh-huh. 4 any reason to dispute that conclusion by the study Q. -- not causal relationships? 5 authors? A. Where is that? Where is that? MR. ARBITBLIT: Object to form. 6 7 THE WITNESS: I agree that Edlund talks about 7 Q. Page 2 of Edlund, 24. 8 MR. ARBITBLIT: Do you have the article? 8 risk factors in a population of individuals who were 9 MR. TSAI: I think she's looking at it. 9 exposed to opioid therapy versus not. 10 Q. BY MR. TSAI: Okay. 10 THE WITNESS: No, I don't have the article. I 11 A. I'm trying to determine the risk of individuals, 11 just have my reference. 12 the odds ratio of developing an opioid use disorder based 12 Q. BY MR. TSAI: Okay. Let's move on. 13 on a certain type of risk factor. 13 So do you agree or disagree with this 14 I'm looking for another place that I cite Edlund 14 statement --15 15 in my report. Give me a moment, please. (Discussion off the record.) 16 Q. Okay. I don't want to spend too much time --MR. TSAI: Let me go off the record real quick. 17 A. Okay. 17 THE VIDEOGRAPHER: Going off the record, the 18 Q. -- given our limited time. So --18 time is 3:18 p.m. 19 A. I did -- I did find it. 19 (Exhibit 7, Pre-roll: Mischa intro, marked for 20 If you'd like me to refer to it, page 73. 20 identification.) 21 21 Q. Okay. Thank you. (Discussion off the record.) 22 A. The Edlund study. 22 THE VIDEOGRAPHER: Back on the record, the time 23 Q. So did you do -- so other than the risk -- the 23 is 3:20 p.m. 24 several risk factors for opioid addiction that we've Q. BY MR. TSAI: So I just wanted to ask you about 24 25 discussed, any others? 25 this interview that you gave. This -- I handed you Page 235 Page 237 MR. ARBITBLIT: I don't think she had finished 1 1 Exhibit 7, which is entitled "Science Versus," from 2 answering the question when she referred to Edlund. You 2 Gimlet Media with Wendy Zukerman. The program is 3 interrupted her. 3 entitled "Opioids, Kicking America's Addiction." 4 THE WITNESS: Do you want me to finish answering 4 Do you recall giving interview for this program? 5 5 your other question? A. Not specifically. Q. BY MR. TSAI: Actually, it seemed like you were Q. Okay. Can you refer to page 4? And I'll direct 7 talking about something a bit different so let me just 7 you to the very top of page 4. And it says: "Anna 8 ask you this: In terms of the several risk factors out 8 Lembke, a psychiatrist at Stanford, was one of those 9 doctors who wasn't keen to treat addicts." 9 there, with respect to opioid addiction did you do any 10 10 analysis of your own in your work in this case to Do you see that? 11 quantify the contribution of these risk factors to opioid 11 A. Yes. 12 addiction in New York specifically? 12 Q. And do you see the abbreviation "AL" henceforth 13 13 under that? MR. ARBITBLIT: Object to form. 14 THE WITNESS: I do not any of my own analyses, 14 A. Yes, I do. 15 Q. Okay. Is "AL" you? 15 but as per my report, including on page 73, Edlund did 16 quantify these risk factors, stating that for chronic 16 A. Yes. Q. Okay. And does this appear to be a correct 17 high-dose opioid use, the odds ratio of approximately 122 17 18 is 40 times greater than for a mental health or alcohol 18 transcription of your interview for this program? 19 use disorder and 15 times higher than for a prior 19 20 20 non-opioid-use disorder. Q. Okay. I just wanted to quickly ask you about on In other words, the chronic use of opioids is 21 page 11, there is a series of footnotes. Number 15 --22 responsible for far more opioid use disorders than the 22 52, sorry, states in email, "Don't let anyone tell you 23 existence of identifiable risk factors for opioid use 23 taking a medication is swapping one addiction for 24 another. It is complete nonsense." 25 25 And the -- that corresponds to a sentence in the Q. BY MR. TSAI: And when Edlund himself says

Page 238 Page 240 1 text saying, "Here's how Anna and other experts think 1 A. Oh, you're not counting both sides? 2 about it." 2 Q. Eight. Eight flips, please. 3 Do you see that? 3 A. Just one? 4 A. Yes. 4 O. Yes, that's one. 5 5 Q. Okay. Do you know if you still have that email? A. Okay. MR. ARBITBLIT: Object to form. That's Q. Since I'm not all that good at reading 6 7 handwriting, I just did -- I did want to just confirm the 7 misrepresenting the evidence. 8 THE WITNESS: I have no idea. 8 accuracy of -- of the notes. MR. ARBITBLIT: It doesn't link this to Anna in Do you see at top it says: "I could control it 10 any way. 10 at first," and then right under that, it says "right 11 Q. BY MR. TSAI: Is it your understanding that you 11 after 9/11"? 12 sent Wendy Zukerman an email with this statement? 12 A. I don't see that at the top. I wonder if I'm on A. I don't have a recollection of having sent that 13 the same page. Okay, yes, I do see that now. 14 email, no. Q. Great. And since you know your handwriting much 15 Q. Okay. Okay. 15 better than I do --A. Right. 16 So you can put that aside. 16 17 A. Okay. 17 Q. -- would you mind reading this particular 18 (Exhibit 8, Handwritten notes, 1/16/14, marked 18 interview, this particular page? 19 for identification.) 19 A. Sure. 20 Q. BY MR. TSAI: So I believe we talked about this 20 "I could control it at first right. After 9/11, 21 at the last deposition, but this is -- I'm handing you 21 huge influx of cheap, super pure, chronic white heroin. 22 what you produced when we requested your -- your notes in 22 \$50 could last me two to three weeks. Am I becoming a 23 connection with writing your book --23 heroin addict? I started reading William Burrough's book 24 A. Uh-huh. 24 to see if it was me. The first time I went into heroin Q. -- Drug Dealer, M.D., do you recall that? 25 25 withdrawal, I didn't know it. I thought I just had the Page 239 Page 241 1 flu. A. Yes, I do. 1 Q. Okay. I'm not actually sure I asked the 2 After two to three months of daily heroin use, I 3 question, but does this -- can you confirm that this 3 went back to California to get away from heroin and get 4 appears to be a true and correct copy of your notes with 4 my life together. I talked to my mom about it. 5 respect to interviewing folks for your book Drug Dealer, Back in New York City, I got buprenorphine as 6 M.D.? 6 intramuscularly injected in a glass vial so I injected 7 A. Yes. 7 and I was doing Buprenex early 2001. It worked well the Q. Okay. Now, there's one -- they're not numbered 8 first time. 8 Moved back to New York. Six months, no heroin, 9 so I want to ask you about --10 MR. TSAI: Actually, can we go off the record. 10 but then I relapsed. Then I used needles to inject 11 THE VIDEOGRAPHER: Going off the record, the 11 heroin using the Buprenex needles. Problems would happen 12 time is 3:24 p.m. 12 when I would go out and have a drink or two, even after a 13 13 party until 2:00 to 4:00 -- 2:00 to 4:00 in the morning, (Discussion off the record.) 14 THE VIDEOGRAPHER: Back on the record, the time 14 at 11:00 p.m. cocaine was useful. 15 15 is 3:25 p.m. I relapsed, alcohol to cocaine to heroin. Today 16 MR. TSAI: Thank you. 16 use to maintenance therapy. Why not just stay on heroin? 17 Tolerance going up and up to the point where I had an 17 Q. So I've handed you -- we're looking at 18 Exhibit 8, your notes in connection with your book. 18 over a hundred dollar a day habit, trouble at school, 19 Could you please turn nine pages from the beginning, and 19 nodding off. 20 I apologize. This doesn't have -- I mean your notes do 20 Q. Okay. Thank you. 21 not have internal pagination. So if you could flip nine 21 And just one point of clarification. On line 3, 22 full pages. 22 when you read "cheap, super pure," is the word after that 23 A. Nine pages from where we were? 23 China? 24 Q. No, from the front. So let's count: One, two, 24 A. Yes. 25 25 three, four, five, six, seven, eight. Q. China, okay.

Page 242 So in your opinion, would this individual have

2 opioid use disorder?

1

A. Yes, this individual had opioid use disorder.

O. And taking this individual as an example, would

- 5 you include this individual in what you've termed your
- 6 dependence effect?
- A. So this individual is actually a great example
- 8 of the tsunami effect, which is to say that although
- 9 she's in a minority group, having started her addiction
- 10 with heroin, we know that's a minority group because more
- 11 than 80 percent, according to Cicero, of heroin users
- 12 today began with a prescription opioid.
- 13 She is somebody who then went from heroin to
- 14 prescription opioids, which resulted in an exacerbation
- 15 of her opioid use disorder, and I describe that several
- 16 pages later, where she was admitted to the hospital for
- 17 an abscess and a skin infection. And if you don't mind,
- 18 I will read from my notes here to get a sense of what
- 19 happened to her afterwards.
- 20 So she -- she was -- I think it's super
- 21 relevant, super relevant to answering your question. So
- 22 if you don't mind, I'd just like to read this short
- 23 passage.

5 the top.

1 you indicated.

24 Q. Okay, sure. Which page is it?

7 just read into the record. Okay.

A. This is just a couple pages after the page that 25

She worried about how people would treat her.

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- 2 Doctors wouldn't work to save my life if they knew I
- 3 wanted to get pain medication. Why is a healthy
- 4 24-year-old -- I can't read something -- dying.
- Then she got IV Dilaudid to treat her pain and
- 6 IV fentanyl. She had huge tolerance because she'd been
- 7 using heroin. She had surgery every other day just
- 8 trying to keep me alive.
- 3.5 five weeks in the ICU. At Stanford three
- 10 months. IV Dilaudid every day. Full -- full anesthesia
- 11 just to do the bandage changes every other day.
- 12 Flesh on calves and feet also rotted off.
- 13 Sedated much of the time. Couldn't walk. Couldn't use
- 14 on my own. IV vanco.
- 15 And then importantly, she spent almost three to
- 16 six months at Stanford. Opioids were part of her daily
- 17 regimen, and then she was given morphine tablets, 20 to
- 18 30 per month, and she was discharged with that high
- volume of pills, which she continued to get.
- 20 She dissolved them in salve and injected them in
- 21 her pic line. So she was not given any addiction
- 22 treatment. There wasn't awareness of her disease.
- 23 Then she got 5150 because the police came along
- 24 and found her heating and injecting her extended-release
- 25 morphine.

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- 2 Q. So two pages after what you just read into the 3 record?
- 4 A. I think so. And you will see "IV fentanyl" at
- Q. That's three pages sequentially after what you
- A. Okay. So actually, just before the IV fentanyl
- 9 page, the prior page you'll see, in the second large
- 10 paragraph, third sentence down, it says she was clean for
- 11 six months. Then she had an infection at her injection
- 12 site, MRSA -- which stands for Methicillan-resistant
- 13 Staphylococcus aureus infection. Her arm was turning
- 14 green and puffy, really scary. Then she relapsed to her
- 15 dad's Dilaudid.
- 16 So, again, a great example of the tsunami
- 17 effect, just the ubiquitous supply of prescription
- 18 opioids in the community.
- She was rushed to Stanford. Delirium, septic.
- 20 Part of her arm rotted off. Didn't tell the doctors
- 21 about the heroin.
- 22 Another great example of why it's so hard for
- 23 front-line doctors to intervene, because they can't get
- 24 the straight story from the patients themselves because
- 25 there's so much stigma around this problem.

1 And that was the first time they realized that I

- 2 was basically suffering from an opioid use disorder.
- But my -- my point in -- I think that's a really
- 4 important piece to include in the story because what we
- 5 have is this very complex relationship between illicit
- 6 opioids, nonmedical use of prescription opioids, and
- 7 legitimate use of prescription opioids. And all of those
- 8 things interweave in really important ways that increase
- 9 the risk of addiction overdose death for all Americans
- 10 and would only have been possible because of the
- 11 increased prescribing and increased supply, the nearly
- 12 ubiquitous access, as a result in part of defendants'
- 13 actions.
- Q. And given this case history that we just
- 15 discussed, would you include this individual within the
- 16 scope of your gateway effect?
- 17 A. This individual wouldn't be included in gateway
- 18 because she didn't begin with a prescription opioid, but
- 19 she certainly would be included in the tsunami effect.
- 20 Q. As well as the dependence effect?
- A. Yes. Because she -- the dependence effect is
- 22 speaking more to those individuals who have developed a
- 23 physiologic dependence to opioids, who don't meet clear
- 24 criteria for an opioid use disorder. So she would really 25 be in the tsunami effect.

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- 1 Q. Okay. Would you include this individual, given
- 2 her case history and her development of addiction while
- 3 she was in New York, within the scope of your -- of New
- 4 York residents whose opioid addiction you would hold
- 5 defendants responsible for?
- 6 MR. ARBITBLIT: Object to form.
- 7 THE WITNESS: So obviously when she was living
- 8 in New York, that's when she started on heroin, not
- 9 prescription opioids. But that doesn't release
- 10 defendants from their responsibility regarding the opioid
- 11 epidemic nationally, including in New York.
- 12 Q. BY MR. TSAI: So you would include this
- 13 individual?
- 14 A. Yes, for the reasons that -- that I described
- 15 having to do with how her opioid addiction was made worse 15
- 16 because of the prescribing of prescription -- because of
- 17 access to prevention opioids that followed her heroin
- 18 use.
- 19 Q. And she wasn't prescribed that particular
- 20 prescription opioid in her case; is that right? She got
- 21 it from her dad. Am I reading that correctly?
- 22 A. No. So -- so there is an instance in which she
- 23 got it from her father. That was the Dilaudid. But then
- 24 she received high doses of opioids inhouse, and she was
- 25 discharged with morphine sulfate, which she then
 - Page 247

- 1 injected.
- Q. Okay. So I'm going to pivot and ask a short
- 3 series of questions now are that specific to my client,
- 4 Mallinckrodt, and then I'll pass to the other attorneys
- 5 who haven't had a chance to ask questions.
- 6 So is your opinion in this case based on any FDA
- 7 warning letter to Mallinckrodt?
- 8 A. I am not aware of any specific FDA warning
- 9 letter to Mallinckrodt; however, I do know that other
- 10 experts will be opining on the FDA.
- 11 Q. Okay. And one of the Mallinckrodt opioid
- 12 medicines that you reference in your report is Xartemis.
- 13 Do you recall that?
- 14 A. Yes
- 15 Q. And do you agree that by 2011, which was before
- 16 Xartemis was even on the market, opioid prescriptions per
- 17 person had begun decreasing in New York?
- 18 MR. ARBITBLIT: Object to form.
- 19 THE WITNESS: I think I do discuss this in my
- 20 report. I'd like to reference my report.
- 21 Q. BY MR. TSAI: I think you're looking, perhaps,
- 22 for page 17 through 18.
- 23 A. Thank you.
- 24 Q. Yeah.
- 25 A. Yes, I am.

- 1 So as I state in my report: "In the state of
- 2 New York, opioid prescribing increased from 101 morphine
- 3 milligram equivalence in 1997 to 442 by 2006 and again
- 4 increased to 492 per person in 2016," which would refute
- 5 your claim that in New York opioid prescribing started to
- 6 decrease around 2011.
 7 It's also true that if you look at the duration
- 8 of the prescription in New York, the length of opioid
- 9 prescriptions actually increased between 2016 and 2017
- 10 from 15 to 19 days of opioids in 2017, an increase of
- 11 25 percent.

14

- 12 O. Okay. Just let me try to understand.
- 13 In your report, you said based on a --
 - (Interruption in proceedings.)
- 5 Q. BY MR. TSAI: I read in your report based on
- 16 IQVA data published by County by the CDC, the opioid
- 17 prescribing rate in Nassau County increased from 46.0 to
- 18 51.1 prescriptions per hundred persons from 2006 to 2011.
- 19 Thereafter, prescribing decreased similarly to the rest
- 20 of New York state, with the rate per 100 persons of 36.0
- 21 in the most recent year of data available, 2017.
- 22 Do you see that?
- 23 A. Yes, I do.
 - Q. That's in your report?
- 25 A. Yes.

24

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- 1 Q. Okay.
- 2 A. Except that I want to say the reason for that
- 3 apparent discrepancy -- it's not an actual discrepancy --
- 4 the CDC data are based on number of prescriptions written
- 5 per 100 persons, whereas that particular New York State
- 6 data is looking at how high the dose was and the length
- 7 of the opioid prescription. So there are different ways
- 8 to measure it.
- 9 So in terms of overall number of prescriptions
- 10 written, those began to decrease around 2011, 2012, but
- 11 the doses appeared to have gone up and the duration of
- 12 prescriptions appear to have gone up.
- 13 Q. I see. Okay.
- 14 Is your opinion in that this case based on
- 15 identifying any specific examples of individuals who
- 16 allegedly became addicted to any opioid as a result of a
- 17 prescription of a Mallinckrodt product in New York?
- 18 A. I don't have specific samples.
- 19 Q. Okay. And similarly, your opinion does not
- 20 identify a single specific overdose death that, in your
- 21 opinion, was allegedly the direct result of the ingestion
- 22 of any opioid made by Mallinckrodt; correct?
- A. Not at that level of specificity, no.
- Q. Okay. Is your opinion in this case based on
- 25 identifying any specific example of a particular opioid

Page 250 Page 252 1 pill made by Mallinckrodt that was a suspicious order 1 A. Yes, I do. 2 diverted improperly? Q. And collectively, I think you referred to it at MR. ARBITBLIT: Object to form. 3 various times as the tsunami effect? THE WITNESS: Not any specific pill. 4 4 A. Yes. 5 Q. Considering access and the supply, did you Q. BY MR. TSAI: Okay. Is your opinion in this 6 consider illicitly manufactured opioids that entered the 6 case based on identifying any specific example of a 7 prescription of a Mallinckrodt opioid written in New York 7 United States illegally? 8 by a doctor or nurse relying on a representation from A. I think that's part of the second and third 9 Mallinckrodt? 9 waves of this epidemic. The increased supply began with 10 A. Not at that level of specificity. 10 prescription opioids, overprescribing, and then created a 11 population of individuals who were addicted to those 11 MR. TSAI: Okay. All right. 12 Let me go off the record, and I will pass the 12 opioids, leading to increased demand, which then promoted 13 witness at this time. Thank you. 13 the illicit market. Including heroin and illicit 14 THE WITNESS: You're welcome. 14 fentanyl. 15 THE VIDEOGRAPHER: Going off the record, the 15 So I think those things are tied in a sequential 16 time is 3:42 p.m. 16 manner. 17 (Discussion off the record.) 17 Q. Would you agree that that supply is not going to 18 (Exhibit 9, JAN-MS-00362490, marked for 18 be disrupted by curbing opioid prescribing presently? MR. ARBITBLIT: Object to form. 19 identification.) 19 20 (Exhibit 10, Highlights of Prescribing 20 THE WITNESS: I disagree with that statement. 21 21 Information, marked for identification.) Q. BY MR. EHSAN: So it is your opinion that even 22 (Exhibit 11, JAN-MS-00362490, marked for 22 if the FDA were to ban the prescribing of all opioids, 23 23 that the supply side that is illicit in its manufacturing identification.) 24 (Exhibit 12, Highlights of Prescribing 24 and distribution would somehow be lessened by that 25 Information, marked for identification.) 25 process? Page 251 Page 253 THE VIDEOGRAPHER: Back on the record, the time 1 1 A. I have never endorsed, nor would I ever endorse 2 is 3:48 p.m. 2 that the FDA should ban prescribing opioids. What I have 3 **EXAMINATION** 3 stated is that the opioids have been overprescribed and Q. BY MR. EHSAN: Good afternoon, Dr. Lembke. We 4 overdistributed and overdispensed, leading to a tsunami 5 met before at your prior deposition. My name is Houman 5 effect. 6 Ehsan. I represent Johnson & Johnson and the Janssen And I do believe that by engaging in safer and 7 defendants. Collectively, that they manufacture 7 more judicious prescribing of prescription opioids, we 8 Duragesic transdermal fentanyl patch and Nucynta or 8 will actually also, potentially in the long, long-term, 9 tapentadol. 9 be able to curb the opioid addiction problem more 10 Doctor, you had talked about an efficient 10 broadly, including addiction to illicit opioids. 11 distribution system earlier today. Q. Do you lay out how the curbing of opioid 12 Do you recall that testimony? 12 prescribing and education, broadly speaking, will in the 13 13 long term reduce the supply of illicitly manufactured A. Yes, I do. 14 Q. Do you consider the US Postal Service to be an 14 opioids abroad? A. The way that I lay that out in the report and in 15 efficient distribution system? 15 16 MR. ARBITBLIT: Object to form. 16 my testimony today is the way in which both nonmedical 17 THE WITNESS: Well, it is a distribution system. 17 use and medical use of prescription opioids are 18 I'm not sure how efficient it is. 18 interwoven and how both independently and together Q. BY MR. EHSAN: Can it reach every small town in 19 greatly increase the risk of an individual turning to a 20 America, rain or shine? 20 illicit source of an opioid. 21 A. I hope so. 21 So by managing the prescription opioid addiction 22 O. You mentioned several times that easy access and 22 oversupply, overdose problem, we will potentially treat 23 supply contributed to the overall opioid epidemic in the 23 the population of addicted persons we have iatrogenically 24 United States. 24 created and then likewise decrease the demand for illicit 25 Do you recall that testimony? 25 opioids imported from elsewhere.

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1 Q. You understand that illicit opioids actually	
2 release non-opioid medications that are sold on the	2 Q. And that is potentially a fatal condition from
3 street as well?	3 excess consumption of water; right?
4 MR. ARBITBLIT: Object to form.	4 A. Yes, it is.
5 THE WITNESS: Yes.	5 Q. Did you, in your clinical practice, ever
6 Q. BY MR. EHSAN: I can ask the question again.	6 encounter patients who have had difficulty making
7 Was that a "yes"?	7 co-payments for the medications that you had prescribed 8 for them?
8 A. Yes.	
9 Q. So someone who may have no exposure to opioids	9 A. Yes, I have.
10 and may be addicted to cocaine may come into contact with	
11 illicitly manufactured opioids, fentanyl, specifically;	11 co-pay be an obstacle to the care of your patients?
12 correct?	12 A. Yes, it can.
13 A. Yes, and they also may come into contact with	Q. Now, you mentioned earlier today that you had
14 illicitly manufactured opioids.	14 reviewed some documents that suggested that McKesson ha
Q. Have you looked at the size of the illicitly	15 provided some free samples of Nucynta.
16 manufactured opioid market in the state of New York for	Do you recall that testimony?
17 your expert opinions today?	17 A. Yes, I do.
18 A. Did you say the illicitly manufactured opioid	18 Q. I want to hand you what's been marked as
19 market?	19 Exhibit 9 (indicating).
Q. Yes, ma'am.	MR. ARBITBLIT: Do you have an extra copy?
A. I have not specifically looked at that market in	21 MR. EHSAN: Yes.
22 the state of New York.	Q. I ask you before we get to that to take a look
Q. Do you know what the approximate market share of	23 at Exhibit 3.
24 Duragesic is in New York?	A. Which one is Exhibit 3?
25 A. No, I do not.	25 Q. Exhibit 3, yes, is your supplemental reliance
Page 255	Page 257
1 Q. Do you know what the approximate market share of	1 list.
2 Nucynta is in the state of New York?	2 Do you see item number 13 there?
3 A. No, I do not.	3 A. Yes.
4 Q. Do you have any historical knowledge of the	4 Q. It is a it says JAN-MS-00864412; correct?
5 market share going back in time?	5 A. It does say that.
6 A. No.	6 Q. And the document I've handed you which has been
7 Q. Do you have a sense of how that market share	7 marked as Exhibit 9 bears that same Bates-stamp; correct?
8 compares to the size of the illicit market in the state	8 A. That's correct.
9 of New York?	9 Q. Is this one of the free samples that you were
10 A. No.	10 referring to regarding Nucynta?
11 Q. You mentioned that even short-term opioid	11 A. Yes, it is.
12 prescriptions are not entirely benign.	Q. I'll draw your attention to a couple of points
13 Do you recall that?	13 on this. Do you see that this document has a date of
14 A. Yes, I do.	14 April 2010 at the bottom in the left-hand column midway
15 Q. Can you identify for me any prescription that	15 through, it says Ortho McNeill Janssen Pharmaceuticals,
16 you've written for that is entirely benign?	16 Inc., 2009. Then next to that, it says April 2010.
17 MR. ARBITBLIT: Object to form.	Do you see that?
18 THE WITNESS: No.	18 A. Yes, I do see that. 19 O. And then is it your opinion, Doctor, that this
19 Q. BY MR. EHSAN: Would you agree with me that even	
20 water is not entirely benign?	20 provided the patient with free samples of Nucynta? 21 And if it helps, you can turn to the next page,
21 MR. ARBITBLIT: Object to form.	
22 THE WITNESS: I would agree that even water is	22 where it says "patient instruction," and item 1 says: 23 "Give your prescription for Nucynta along with this
23 not entirely benign. 24 O. BY MR. EHSAN: As a psychiatrist, did you have	24 attached savings card to your pharmacist."
24 Q. BY MR. EHSAN: As a psychiatrist, did you have 25 occasion to ever treat someone with diabetes insipidus?	24 attached savings card to your pharmacist. 25 A. Right. So this is a coupon my understanding
	123 A. Kight. So this is a coupon my understanding

HIGHLY CONFIDENTIAL Page 258 Page 260 1 is that this is a coupon that allows the patient to be 1 I'm going to hand you what's been marked as 2 able to pay less for their Nucynta prescription. 2 Exhibit 10 (indicating). I will show you that. Q. And do you think that's equivalent to a free So this is the -- I'll represent to you this is 4 sample? 4 the very first label, which is the approval for 5 A. Yeah, I think that could be equivalent to a free 5 tapentadol under the tradename Nucynta. In fact, this 6 sample. 6 one doesn't even have the tradename in the label yet, but 7 7 it is tapentadol. Q. And you understand that Nucynta is a Schedule II 8 opioid? And you'll see the initial US approval was 2008, 9 9 and that this particular document was revised in November A. Yes, I do. 10 Q. Are you aware whether or not Schedule II opioids 10 of 2008. 11 can be given as free samples? 11 Do you see that? A. Well, this is a way to undercut the Schedule II 12 A. Where does it say it was revised? Oh, down 13 regulations to make opioids more readily available. But 13 below. 14 more importantly, I cite this document as an example of 14 Q. Yes. 15 15 the ways in which opioid distributors such as McKesson A. I see that. 16 and opioid manufacturers such as Janssen have worked in 16 Q. If you look at the indications of use, again, 17 collaboration to promote opioid prescribing, contributing 17 the trade name is missing in this early label, but is an 18 to the oversupply problem. 18 opioid analgesic indicated for the relief of moderate to Q. So if a doctor writes a prescription for Nucynta 19 severe acute pain in patients 18 years or older. 20 20 and a patient uses this coupon to reduce his or her Do you see that? 21 21 co-pay, you see that as a nefarious thing? A. I do see that. 22 A. In isolation, not necessarily. But in the 22 Q. Okay. So would this indicate at least that 23 broader picture of the conduct of defendants, yes, to me 23 there is a version of Nucynta that only has an acute pain 24 this is worrisome, especially when it seems to me that 24 indication? 25 the various defendants are trying to say that the other 25 A. This would assert that this version of Nucynta Page 259 Page 261 1 one is to blame, when, in fact, they are working with one 1 has an acute pain indication. 2 another. Q. And do you see where the dosage forms and 3 3 strengths of the tablets are available in 50, 75 and MR. EHSAN: Move to strike that -- the rest of 4 your response after the beginning as nonresponsive. 4 100 milligrams? 5 Q. Doctor, do you know what Nycynta's mechanism of A. I do see that, yes. 6 action is? Q. Okay. You can put that aside. I'm going to 7 A. Yes, I do. 7 show you one more document here (indicating). This is 8 Exhibit 11. 8 Q. What is Nucynta's mechanism of action? 9 9 A. It's a norepinephrine reuptake inhibitor. And do you see that this is another coupon 10 Q. And you understand if Nucynta is indicated for 10 where -- that the top states up to ten free pills of 11 Nucynta, 50, 75 or 100 milligram. 11 acute or chronic pain? 12 MR. ARBITBLIT: Object to the form. 12 Do you see that? THE WITNESS: Well, when you say is indicated 13 A. I do see that. 14 for acute or chronic pain, what are you basing that on? 14 Q. And it says, again to the patient, that present Q. BY MR. EHSAN: You understand drugs come with 15 15 your written prescription for Nucynta. 16 indications? 16 Do you see that? 17 17 A. Yes, I do. A. Present your written prescription for up to ten Q. Do you know that this particular Nucynta coupon, 18 Nucynta.

> A. I would just -- I would just add for 23 completeness, this voucher to your pharmacist, give this

Q. These dosages would be consistent --

Q. 50, 75 or 100 milligram tablets; correct?

24 voucher to your pharmacist to receive your free trial. 25 Q. Again, but it requires a prescription for

19

20

21

22

A. Yes.

23 It was based on what?

20

19 is it for a Nucynta that's indicated for chronic pain?

THE WITNESS: I'd like to see the source that

22 Janssen relied upon to promote Nucynta for chronic pain.

Q. BY MR. EHSAN: Again, I don't think you

MR. ARBITBLIT: Object to form.

25 understood my question so let me try it this way.

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1 Nucynta; correct?

- 2 A. (Nods head.)
- 3 Q. And presumably that doctor has made a decision
- 4 that Nucynta is an appropriate medication for acute
- 5 treatment of pain in that patient; correct?
- 6 MR. ARBITBLIT: Object to form.
- 7 Q. BY MR. EHSAN: Is that a "yes"?
- 8 A. Yes.
- 9 Q. And that this allows the patient to offset the
- 10 cost of the medication; correct?
- 11 A. It allows for a free trial.
- 12 Q. Would that mean that -- so assume this coupon
- 13 didn't exist. Would you then advocate that the patient
- 14 not take the medication because he or she can't afford 15 it?
- 16 MR. ARBITBLIT: Object to form.
- 17 THE WITNESS: I'd really have to know the
- 18 details of the specific case in order to weigh in on that
- 19 question.
- 20 Q. BY MR. EHSAN: So you can't say that it would be
- 21 better for the patient to get the medication he or she
- 22 was prescribed or not be able to afford it? That
- 23 requires more information to make that distinction?

1 pattern of opioid prescribing in the last ten years, I

2 can't be certain that this patient should actually be3 prescribed an opioid analgesic, even for acute pain.

24 MR. ARBITBLIT: Object to form.

6 for the treatment of acute pain?

9 the risk-benefit calculation.

13 Exhibit 12 (indicating).

10

12

19 correct?

20

21

23

22 that.

25 THE WITNESS: Yes. Because given the prevailing

Q. BY MR. EHSAN: Do you agree that there are

5 randomized clinical trials showing efficacy of opioids

A. I do. But it doesn't mean that opioids are

Q. Understood. We, I think, established that

I'm going to hand you what's been marked as

And Doctor, I'll represent to you this is the

8 without risk, even in an acute setting. It's all about

11 there's a risk associated with every prescription.

15 first or approval prescription -- or sorry -- labeling

This would be Exhibit 9.

16 for Nucynta ER, which is the long-acting version of

17 Nucynta, and it was actually approved in 2011, and that

18 by dating purposes, it postdates the April 2010 coupon;

A. April 2010 and 2011, yes, it appears to postdate

Q. And likewise, if you look at the dosage forms

24 and strengths, it's not available in a 75-milligram

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- 1 A. Where are the dosages forms and strengths?
- 2 Q. So sure. Left-hand column, next-to-last
- 3 segment.
- 4 A. 50, 100, 150, 200, 250. No, it's not available
- 5 in 75.
- 6 Q. So likewise, what I handed you in Exhibit 11
- 7 would be inconsistent with a reference to the long-acting
- 8 version of Nucynta; correct?
- 9 A. Not necessarily because it is available in 50 10 and 100.
- 11 Q. So you're suggesting the coupon is referring to
- 12 two different Nycyntas in the same construct? If that's
- 13 your understanding, that's fine. I'm not going to take
- 14 time to debate that issue, but is that your opinion?
- 15 A. Well, it's not -- it's not clear to me which
- 16 Nucynta the coupon is referring to.
- 17 Q. Okay. Now, Doctor, if you don't mind looking at
- 18 again the very first page of Exhibit 12, do you see there
- 19 is an indication and usage section?
- 20 A. Yes, I do.
- Q. Would you mind reading that, please.
- 22 A. "Nucynta ER is an opioid analgesic indicated for
- 23 the management of moderate to severe chronic pain in
- 24 adults whom continuous around-the-clock opioid analgesic
- 25 is needed for an extended period of time."

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- 1 Q. Would you agree with me, Doctor, that that
- 2 indication is for the use of Nucynta in the management of
- 3 chronic pain?
- 4 MR. ARBITBLIT: Object to form.
- 5 THE WITNESS: Yes.
- 6 Q. BY MR. EHSAN: Now, do you agree with this
- 7 indication for Nucynta?
- 8 A. I think this indication is not supported by the
- 9 evidence. I do reference some of the efficacy studies in
- 10 my report. Afilalo, et al., compared Nucynta to placebo
- 11 and I believe oxycodone and found no clinically
- 12 meaningful difference in a 12-week study.
- And as far as I know, there are no studies that
- 14 are placebo-controlled randomized trials longer than
- 15 12 weeks using Nucynta, tapentadol, in the treatment of
- 16 chronic pain.
- 17 So I feel that this indication is not informed
- 18 by the evidence.
- 19 Q. I'll just -- two quick questions, and I realize
- 20 I'm trying to make things quick here, given the timing.
- 21 But the Afilalo study references or comparing
- 22 Nucynta to oxycodone, another active opioid; right?
- A. Yes, and to placebo.
- Q. Could you turn to page 12 of Exhibit 3 that I
- 25 handed you. That's the label for the long-acting

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25 version, is it?

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1 Nucynta. You have it, I think.

- 2 A. I have it? Okay, yes.
- 3 Q. If you turn to page 3 of that document. You
- 4 have it.
- 5 Do you see that there is a series of warnings
- 6 surrounded by a box?
- 7 A. Yes, I do.
- 8 Q. Are you familiar with the term "box warning" or
- 9 "black box warning"?
- 10 A. Yes, I am.
- 11 Q. Do you see in the middle of that black box
- 12 warning related to Nucynta ER, there's a section titled
- 13 "Proper Patient Selection"?
- 14 A. Uh-huh.
- 15 Q. Could you please read that.
- 16 A. "Nucynta is an extended-release formulation of
- 17 tapentadol indicated for the management of moderate to
- 18 severe chronic pain in adults when a continuous
- 19 around-the-clock opioid analgesic is needed for an
- 20 extended period of time."
- Q. Do you feel -- you believe that is a false or
- 22 misleading statement?
- A. I feel that this statement is not informed by
- 24 reliable evidence because it takes a study that provides
- 25 weak evidence for efficacy in acute pain and presumably
 - Page 267
- 1 extends that to the treatment of chronic pain.
- Q. Do you have an understanding of what studies the
- 3 FDA reviewed in its approval and ultimate decision for
- 4 the indication of Nucynta ER?
- 5 A. I believe that they did base their approval on
- 6 the Afilalo study and I think also the Buynak study in 7 2010.
- 0 0
- 8 Q. And you think the totality of the evidence that
- 9 the FDA reviewed in connection with the indication for
- 10 Nucynta ER does not support the indication the FDA
- 11 ultimately granted Janssen for the drug; is that correct?
- 12 A. Yes, I would say that's true.
- 13 Q. Would you think that the FDA was just wrong on
- 14 this issue?
- 15 A. I think the FDA was wrong on this issue, yes.
- 16 But there are other experts who will be opining on the
- 17 FDA and on FDA labeling.
- 18 Q. Focusing your attention on the indication for
- 19 Nucynta ER, it talks about management of moderate to
- 20 severe chronic pain when a continuous around-the-clock
- 21 opioid is needed.
- 22 Do you see that?
- A. This is under "proper patient selection" again?
- 24 Q. No. If you go back to page 1. I apologize for
- 25 not being very clear. Under the "indication" section.

- 1 A. Yes.
- Q. Now, how would a physician know that a patient
- 3 required around-the-clock or continuous opioid analgesic?
- 4 MR. ARBITBLIT: Object to form.
- 5 THE WITNESS: I guess could you be more specific
- 6 in your question? It seems that the question could
- 7 encompass many different clinical scenarios.
- 8 Q. BY MR. EHSAN: Sure. Let me just tell you --
- 9 put it differently.
- Would it be fair to say that in order for
- 11 someone to require around-the-clock opioid analgesic, he
- 12 would qualify for the indication under Nucynta, that he
- 13 or she would have to be on some amount of opioids before
- 14 getting to the Nucynta prescription?
- 5 A. Are you asking me about my opinion regarding the
- 16 use of opioids in the treatment of chronic pain or are
- 17 you asking me about the common practice?
- 18 Q. Dr. Lembke, you said you had 20 years of
- 19 practice or medical practice experience and you relied on
- 20 your other clinical judgement, and I'm just taking it
- 21 from a perspective of a physician who's prescribed
- 22 opioids as well, that you don't start someone with a dose
- 23 of a long-acting, continuous opioid unless you know how
- 24 much opioids they could tolerate, i.e., they should
- 25 probably be on some level of regular short-acting opioids

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- 1 and you're transitioning them to a long-acting opioid.
- 2 MR. ARBITBLIT: Object to form.
- THE WITNESS: So I'm not sure that the actual
- 4 practice as it occurs in the United States necessarily
- 5 follows what you just said. I think that patients are
- 6 started on long-acting opioids by some physicians even
- 7 when they've not been on short-acting opioids, so...
- 8 Q. BY MR. EHSAN: Understood. And I'm sorry, it
- 9 was suggested that the United States meaning that I don't
- 10 have experience with the practice in the United States or
- 11 are you just saying that you have a different sense of
- 12 where I've come from in terms of my clinical experience
- 13 versus yours? I'm just curious about that.
- 14 A. I know nothing about your clinical experience.
- 15 Q. But you believe in the United States it is not
- 16 standard practice to take a patient first on a
- 17 short-acting opioid, then transition them to a
- 18 long-acting opioid?
- 19 A. I think that practice varies greatly and that we
- 20 are in a situation where many doctors without pain
- 21 expertise, in particular front-line primary care doctors,
- 22 have been put in the position of prescribing opioids
- 23 without really being given proper training on how to do
- 24 that, and so I think practice patterns vary greatly.
- 25 Q. Do you know anything about the specific practice

Page 270 Page 272 1 patterns in New York? 1 by Janssen or any of its affiliates to the prescribing A. I've commented previously on New York and what I 2. doctor? 3 have looked at and what I haven't looked at. 3 MR. ARBITBLIT: Object to form. O. Two -- two more quick questions. THE WITNESS: I believe that Janssen and Janssen Doctor, you said you worked with a DEA agent in 5 affiliates' misrepresentation have impacted prescribers 6 Oakland recently. 6 in New York. 7 Do you recall that? Q. BY MR. EHSAN: But can you identify a single 8 A. Correct. 8 doctor that was misled by Janssen? Q. Would you be willing to provide that agent's A. Yes, I can identify doctors that I have spoken 10 name? 10 to in New York who said that they were misled by the 11 A. I'd be happy to do that. 11 misrepresentations by the opioid pharmaceutical industry, 12 Q. Okay. Can you provide that? 12 including Janssen, but not specifically referring to 13 A. I'd have to look at my records. I --14 MR. EHSAN: Fair point. Q. So none of them specifically mentioned Janssen? 15 And I'd just ask your counsel that if Dr. Lembke 15 16 could provide that name, that you could provide it to us. 16 MR. EHSAN: Thank you, Doctor. I will pass the 17 MR. ARBITBLIT: If the agent himself or herself 17 witness. 18 has no reason to object, then I would have no reason to 18 THE VIDEOGRAPHER: Going off the record, the 19 object. And I don't know whether the witness has the 19 time is 4:17 p.m. 20 right to speak for that person. 20 (Recess.) 21 If she's willing and the agent that she spoke to 21 THE VIDEOGRAPHER: Back on the record, 4:25 p.m. 22 is willing, then I'm willing. 22 **EXAMINATION** 23 MR. EHSAN: Well, I asked her a question. She 23 Q. BY MS. VICARI: Dr. Lembke, my name is Angela 24 said she was willing. 24 Vicari, and I represent the ENDO and Par defendants in 25 MR. ARBITBLIT: And you asked me a question and 25 this case. Page 271 Page 273 1 I gave you an answer. She may not have the authority to 1 Do you know what opioid medication --2 speak for that person. 2 medications ENDO manufactures? 3 A. Yes. ENDO manufactures OPANA ER, Percodin, MR. EHSAN: Under what --MR. ARBITBLIT: I don't know. I'm not saying 4 Percocet, and generic forms of oxycodone, oxymorphone, 5 that I won't provide it. You're just making an argument 5 hydromorphone and hydrocodone. 6 that doesn't necessarily have a basis. We may be in Q. Do you know what opioid medications Par 7 complete agreement. 7 manufactures? Q. BY MR. EHSAN: Then, Dr. Lembke, are you aware A. I'm not familiar with the ways in which ENDO and 8 9 of any marketing by Janssen that led to any inappropriate 9 Par relate to each other, but it could be that some of 10 prescription for Duragesic or Nucynta in the state of New 10 those are, in fact, manufactured by Par or were 11 York? 11 manufactured by Par before being acquired by ENDO. I'm 12 A. So I'm aware of marketing efforts by Janssen and 12 not familiar with the acquisitions process. 13 lobbying efforts and funding efforts by Janssen on a 13 Q. And I noticed in answering that question, you're 14 national level that did affect prescribing patterns 14 referring to a document. Is that document part of your 15 across all the states, including the state of New York. 15 report? Q. Let me be a little more specific. 16 16 A. This document is part of the Complaint. 17 Can you identify a single prescription in the 17 MS. VICARI: Can we mark that. I'd like to mark 18 state of New York for either Duragesic or Nucynta that 18 that as an exhibit in the deposition. 19 was -- let's just take it sequentially -- that was, one, 19 I'd like to mark that document as Exhibit Number 20 improper? 20 13. Oh, it's already marked as 5? 21 A. I'm not --21 MR. ARBITBLIT: It's part of the exhibit that 22 MR. ARBITBLIT: Object to form. 22 counsel asked earlier that we reproduce for you. So it's 23 THE WITNESS: At that level of specificity, no, 23 part of Exhibit 5. 24 24 not a single prescription. MS. VICARI: Okay. Thank you. Q. BY MR. EHSAN: Two, based on a misrepresentation 25 Q. Now, Dr. Lembke, is it your understanding that

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1 other experts are offering opinions regarding the

- 2 adequacy of ENDO's suspicious order monitoring systems?
- 3 A. Yes
- 4 Q. And you're not offering any opinions regarding
- 5 the adequacy of ENDO's suspicious order monitoring
- 6 systems; correct?
- 7 A. I'm not offering specific opinions on ENDO, but
- 8 as stated in my report, I do offer an opinion on the role
- 9 of distributors, manufacturers and pharmacies in creating
- 10 the oversupply that led to the opioid epidemic.
- 11 Q. Do you know anything about the way in which ENDO
- 12 monitored suspicious orders?
- 13 A. I know that in general, opioid manufacturers
- $14\,$ look at reports of -- actually, I would -- I would defer
- 15 that to other experts.
- 16 Q. So you're not offering any opinions regarding
- 17 the adequacy of ENDO's suspicious order monitoring
- 18 system; correct?
- 19 A. That's correct.
- 20 Q. And you're not offering any opinions regarding
- 21 the adequacy of Par's suspicious order monitoring
- 22 systems; correct?

1

3

10

19

- 23 A. That's correct.
- 24 Q. And you said earlier other experts will be

2 places. If you'd like, I can go to those sections.

A. I do mention the FDA in my report in several

You're not offering any opinions regarding

Q. And you're not offering any opinions regarding

Q. Now, Dr. Lembke, all the documents that you

A. That is correct, but I would add to that I was

15 the recipient of ENDO and other defendants' marketing

16 material throughout my medical career. Those are not --

Q. And what documents that are not listed in

23 of opioid manufacturers and their influence on pain as

24 the fifth vital sign on the Federation of State Medical

25 Boards on pain guidelines, I was the recipient of those

20 Exhibit B or the supplement did you receive from ENDO

A. I can't speak to ENDO specifically, but in terms

17 those are not listed, but those are part of what has

21 during the course of your medical career?

5 ENDO's compliance with FDA regulations; correct?

8 Par's compliance with FDA regulations; correct?

11 considered in forming your opinions are set forth in

12 Exhibit B to your report and the supplement that was

25 opining on FDA issues; is that correct?

Q. My -- that's okay.

A. That's correct.

A. That is correct.

13 provided last night; correct?

18 contributed to my opinion.

1 marketing efforts.

- 2 Q. And a lot of those materials are in your report.
- 3 I was asking which materials that are not in Exhibit B or
- 4 the supplement to your report did you receive from ENDO?

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- 5 MR. ARBITBLIT: Object to form.
- 6 THE WITNESS: As answered, the materials that
- 7 are cited in my report as well as my clinical experience
- 8 and my experience as a clinician being influenced by the
- 9 marketing material in real time as it unfolded in the
- 10 '90s and early aughts through today have contributed to
- 11 my opinion.
- So I wouldn't want you to be under the mistaken
- 13 conclusion that it's just those listed documents gathered
- 14 for the purpose of writing the report.
- 15 Q. BY MS. VICARI: Do you intend to offer opinions
- 16 at trial regarding ENDO -- any ENDO documents that are
- 17 not included in Exhibit B or the supplement to your
- 18 report?
- 19 A. If there's a document that you'd like me to see
- 20 in addition, I would be happy to review it.
- Q. There's no document that I wish to show you.
- 22 Sitting here today, do you intend to offer any
- 23 opinions at trial concerning any ENDO documents that are
- 24 not included in Exhibit B or the supplement to your
- 25 report?

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- 1 A. Not unless I'm asked to review an additional
- 2 document, which I would be happy to do.
 - 3 Q. And in forming your opinions as to ENDO in this
 - 4 case, you did not consider any deposition testimony given
 - 5 by ENDO witnesses; is that correct?
 - 6 A. That is correct.
 - 7 Q. And in forming your opinions in this case, you
 - 8 did not consider any deposition testimony given by any
 - 9 Par witnesses; is that correct?
 - 10 A. That is correct.
 - 11 Q. And it's fair to say that in forming your
 - 12 opinions, you didn't review all of ENDO's opioid
 - 13 marketing materials; correct?
 - 14 A. That is correct.
 - 15 Q. To the extent that you considered ENDO documents
 - 16 in forming your opinions, you've reviewed those documents
 - 17 thoroughly; correct?
 - 18 A. Yes.
 - 19 Q. And to the extent that as a result of your
 - 20 review of an ENDO document, did you include all of the
 - 21 statements that you believe to be misleading in your
 - 22 report?
 - 23 A. I included representative samples. I didn't
 - 24 include all of the misleading documents. There were so
 - 25 many that it would have been a very long report to

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include all of them, but I included representative
 examples.
 Q. Which ENDO documents -- in your opinion, which

- 4 ENDO documents contained misleading statements that were
- 4 ENDO documents contained misleading statements that we
- 5 not included in Exhibit B to your report or the
- 6 supplement?
- 7 MR. ARBITBLIT: Object to form.
- 8 THE WITNESS: I don't remember now, but when I
- 9 found a statement that was repetitive of other
- 10 misrepresentations, I just tried to use several examples,
- 11 not every single example, because it would have been
- 12 redundant.
- 13 Q. BY MS. VICARI: Dr. Lembke, you have not
- 14 conducted any analyses to determine which, if any,
- 15 prescriptions of ENDO opioid medications in New York
- 16 state were medically inappropriate, have you?
- 17 MR. ARBITBLIT: Object to form.
- 18 THE WITNESS: As stated before along similar
- 19 lines of questioning, I have not analyzed documents at
- 20 the level of individual documents produced by ENDO in the
- 21 state of New York. But I would qualify that by saying I
- 22 believe that prescribers in the state of New York were
- 23 exposed to the same misleading marketing messages as
- 24 doctors all across the country.
- Q. BY MS. VICARI: And same question as to Suffolk

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- 1 prescribing physicians are a window into the campaign
- 2 that ENDO and other defendants were launching to convince
- 3 prescribers.
- 4 I think there were many instances of
- 5 misrepresentation for which there's documentation at all,
- 6 and of course, those can't be included.
- 7 Q. I guess my -- my question was not as to
- 8 messaging; it was to the particular document.
- 9 Is it your -- you would agree with me that any
- 10 ENDO document that was internal only and never seen by a
- 11 physician, that document could not have been relied on by
- 12 a physician in making a prescribing decision; correct?
- 13 MR. ARBITBLIT: Object to form.
 - THE WITNESS: Well, I disagree with that because
- 15 an internal ENDO document could easily have influenced
- 16 the external communications with prescribers and hence
- 17 influence their prescribing.
- 18 Q. BY MS. VICARI: Dr. Lembke, can you identify for
- 19 me any individuals who died as a result of taking an
- 20 opioid manufactured by either ENDO or Par in either the
- 21 state of New York, Suffolk County or Nassau County?
- 22 A. No.

14

- 23 Q. And Dr. Lembke, can you identify for me any
- 24 individuals who overdosed on an opioid manufactured by
- 25 ENDO or Par in New York state, Suffolk County or Nassau

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- 1 County. Is your answer the same?
- A. Same answer.
- 3 Q. And same question as to Nassau County. Is your
- 4 answer the same?
- 5 A. Same answer.
- 6 Q. You have not conducted any analysis to determine
- 7 when -- whether any particular prescription of an ENDO
- 8 medication in New York state was influenced by ENDO's
- 9 marketing; correct?
- 10 MR. ARBITBLIT: Object to form.
- 11 THE WITNESS: I would refer to my answer to the
- 12 last question, which I think is essentially the same
- 13 answer.
- 14 Q. BY MS. VICARI: And same question as to Suffolk.
- 15 Is your answer -- is your answer the same?
- 16 A. Yes, it is.
- 17 Q. Okay. And the same question as to Nassau
- 18 County. Is your answer the same?
- 19 A. Yes, it is.
- Q. Dr. Lembke, would you agree with me that any
- 21 ENDO document that was an internal-only document, not
- 22 seen by physicians, could not have been relied on by
- 23 doctors in New York state in their prescription of an
- 24 opioid to a patient?
- 25 A. Well, I think internal documents not seen by a

- 1 County?
- 2 A. Not at the level of an individual by name. Not
- 3 at that level.
- 4 Q. Okay. And if I asked the same question with
- 5 respect to abuse of an ENDO or Par opioid, is your answer
- 6 the same?
- 7 A. Yes.
- 8 Q. Okay. And you can't identify for me anyone who
- 9 misused an ENDO or Par opioid in the state of New York,
- 10 Suffolk County or Nassau County, can you?
- 11 A. Not by name, no.
- 12 Q. And similarly, you can't identify any individual
- 13 who became addicted to an ENDO or Par opioid in the state
- 14 of New York, Suffolk County or Nassau County; correct?
- 15 A. Correct.
- Q. Now, Dr. Lembke, when you encounter a patient
- 17 who you learn has abused a prescription opioid, do you
- 18 report that abuse as an adverse event to the manufacturer
- 19 of that opioid?
- A. I have not done that, no.
- Q. And when you encounter a patient who you know
- 22 misused a prescription opioid, do you report that as an
- 23 adverse event to the manufacturer of the opioid?
- A. I've not taken that action, but I have written
- 25 and spoken widely on the problem of prescription opioid

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1 misuse and addictive use as a way to try to raise

- 2 awareness. So I have taken other measures to raise
- 3 awareness.
- 4 Q. But you haven't submitted an adverse event
- 5 report to the manufacturer in that case; correct?
- A. No, I haven't, and that is largely because my
- 7 awareness of the opioid problem really began after I
- 8 graduated from medical school and finished my residency
- 9 training, and at that point, I was not prescribing
- 10 opioids until I began to prescribe buprenorphine for the
- 11 treatment of opioid use disorder.
- 12 Q. Well, when patients come to you for the
- 13 treatment of opioid use disorder today, you testified
- 14 earlier some of them are abusing prescription opioids;
- 15 correct?
- 16 A. Yes, that is true.
- 17 Q. And do they tell you which opioid they are
- 18 abusing?
- 19 A. Sometimes they do, yes.
- 20 Q. And when they tell you which opioid and they
- 21 are, I'll say, misusing, do you report that as an adverse
- 22 event to the manufacturer of that opioid?
- A. That has not been my practice.
- Q. And when you encounter a patient who you know
- 25 has become addicted to a prescription opioid, do you

- 1 A. Yes.
 - 2 Q. How would you design a randomized
 - 3 placebo-controlled trial to determine whether opioid

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- 4 therapy is effective for chronic non-cancer pain?
- 5 A. Well, I would try to use a real clinic
- 6 population, not a rarified sample. So I would try to
- 7 base it in a clinic and recruit patients who were
- 8 representative of the types of patients we see in real
- 9 clinical care.
- 10 I would try, as the SPACE trial did, to assess
- 11 their impressions of opioids prior to initiating therapy.
- 12 I would randomize those individuals to
- 13 comparable groups, one group to receive opioids and
- 14 another to receive placebo in a blinded -- double-blinded
- 15 fashion, so neither the providers -- prescribers or
- 16 patients themselves knew which they were getting.
- 17 Q. Uh-huh.
- 18 A. And then I would try to use comprehensive
- 19 measures that are clinically meaningful to assess their
- 20 subjective pain relief but also their objective function
- 21 and many other potential adverse health consequences,
- 22 including the risk of misuse and addictive use. That's
- 23 just a start.
- Q. You mentioned the SPACE trial. Do you believe
- 25 that there was any selection bias in the SPACE trial?

- 1 report that case of addiction to the manufacturer of the
- 2 opioid as an adverse event report?
- 3 A. I don't report it as an adverse event report to
- 4 the manufacturer, but I certainly do alert the other
- 5 healthcare providers taking care of that patient. I
- 6 alert in some instances the pharmacist who's dispensing
- 7 for that patient.
- 8 Q. And do you report any known diversion of a
- 9 prescription opioid to the manufacturer as an adverse 10 event?
- 11 A. As stated before, it's very hard for me to be
- 12 aware of diversion in real time because patients will not
- 13 admit to it. It's only in the past tense that they'll
- 14 admit to it. I've had instances of being suspicious of
- 15 diversion, but not enough to, let's say, involve criminal
- 16 justice or report it at that level.
- 17 Q. Now, Dr. Lembke, it's your position and your
- 18 opinion in this case that there's no reliable scientific
- 19 evidence showing that the long -- that long-term opioid
- 20 therapy is effective for chronic non-cancer pain; is that
- 21 correct?
- A. Yes, that's correct.
- Q. And by "reliable scientific evidence," you mean
- 24 a randomized placebo-controlled trial in excess of three
- 25 months; is that correct?

- 1 A. So the SPACE trial itself said that there was
- 2 some bias in favor of opioids a priori.
- 3 Q. Is that the only bias that you're aware of in
- 4 the SPACE trial?
- 5 A. Well, the SPACE trial used an opioid-naive
- 6 sample. That's not a bias, but there are lots of
- 7 patients who are already on opioids that should also be
- 8 counted.
- 9 And, of course, you know, 12 months, although a
- 10 long time compared to most studies, is still probably not
- 11 sufficient to assess the true risk of opioid addiction.
- 12 When patients are receiving prescription for an opioid in
- 13 clinical care, there are data showing that median length
- 14 of time to developing an opioid addiction is
- 15 approximately three years.
- MS. VICARI: Thank you, Dr. Lembke, for your
- 17 time. I'll pass the witness.
- Can we go off the record while we pass the
- 19 witness.
- 20 MR. ARBITBLIT: Yes, thanks for asking.
- 21 THE VIDEOGRAPHER: Going off the record, the
- 22 time is 4:42 p.m.
- 23 (Discussion off the record.)
- 24 (Exhibit 13, ALLERGAN_MDL_01361692 1850,
- 25 marked for identification.)

Page 286 Page 288 1 (Exhibit 14, WIS_PPSG_003892, marked for 1 A. No. 2 identification.) Q. Now you, as was mentioned, did serve a report in 3 THE VIDEOGRAPHER: Back on the record, the time 3 the MDL case as well. 4 is 4:45 p.m. Do you recall that? 5 **EXAMINATION** A. Yes. Q. BY MS. RIVERA: Good afternoon, Dr. Lembke. 6 Q. Okay. And I'll represent to you that in that 7 A. Good afternoon. 7 case, you listed only five Allergan Bates-labeled 8 Q. My name is Maria Rivera. I'm from the law firm 8 documents. And the document that you added is number 667 9 of Kirkland & Ellis, and I represent Allergan Finance, 9 in your New York report, and I'm going to hand that to 10 LLC, in this case. 10 you, which has been marked Exhibit 13 (indicating.) 11 If you wouldn't mind in Exhibit 2, which is your MR. ARBITBLIT: Thank you, Counsel. 11 12 report, turning to Appendix B, which is your relied upon 12 O. BY MS. RIVERA: And let me just back up and ask 13 list. 13 you one question. 14 And if you would turn to page 49 of that relied 14 Were the six Allergan-produced documents that 15 upon list, please. 15 you reviewed provided to you by your counsel? 16 A. 49 of the relied upon list. Yes, I'm there. 16 A. Yes, they were. 17 Q. Yes, ma'am. 17 Q. Okay. And do you have an understanding that 18 Am I correct that this is where you list the 18 Allergan has produced hundreds of thousands of documents 19 document -- or the defendant-specific documents that you 19 in this case; correct? 20 reviewed and relied upon in reaching your opinions in 20 A. That is correct. 21 Q. But you didn't think it was necessary to review 22 A. Yes, this is the documents that I relied upon. 22 any more Allergan documents that the six that are listed 23 Q. Okay. And am I correct that there are six 23 in your report; is that correct? 24 Allergan-produced documents on that list? 24 MR. ARBITBLIT: Object to form. 25 A. Yes. 25 THE WITNESS: I lived through this promotional Page 287 Page 289 Q. Okay. So is it fair to say that those are the 1 campaign, and the Allergan documents that I reviewed were 1 2 only Allergan-specific documents that you reviewed to 2 consistent with my lived experience of pharmaceuticals' 3 promotional messages. So because those themes were 3 reach any Allergan-specific opinions in your report? A. No, because I was the recipient of multiple 4 saturated, no, I didn't think it was necessary. But if 5 Allergan promotional material throughout my medical 5 there are any documents that you would like me to review, 6 career. So that is also part of what forms the basis of 6 I would be happy to review them. 7 my opinion. Q. BY MS. RIVERA: Okay. But the answer to my Q. Okay. Can you identify any specific Allergan 8 question about whether you didn't think it was necessary 9 promotional material that you received during your career 9 to review any more Allergan documents that the ones that 10 that you're relying upon for purposes of your opinions in 10 are listed in Appendix B is "yes"; correct? 11 this case? 11 MR. ARBITBLIT: Object to form, asked and 12 12 answered. A. I do have some memories of Allergan promotional 13 material for Actiq or fentanyl lollipops through my 13 THE WITNESS: I did answer that question. 14 medical training because I remember being so shocked that Q. BY MS. RIVERA: Okay. The document that I 15 handed you, which is Exhibit 13, is the one that you 15 fentanyl would be put in lollypop form. Q. And is it your understanding that those are 16 added to your report. 17 17 Allergan products? In looking at this document, which is entitled 18 "ER/LA Opioid REMS," do you see that this document was A. Oh, sorry. Those are Teva products. You're 19 right. Sorry. 19 created by The Collaboration For REMS Education? 20 Q. Okay. So let me ask my question again. 20 A. Yes, I do. Do you have or can you identify any other Q. Okay. So in looking at this document, would you 22 Allergan-specific documents or materials that you're 22 agree with me that is not a document that Allergan 23 relying upon for your opinions in this case with respect 23 created? 24 24 to Allergan, other than the six documents that are listed A. I can't be sure of that. I'm not sure what The 25 Collaborative For REMS Education consists. 25 in Appendix B to your report?

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- 1 Q. Are you able to tell whether any statements in
- 2 this presentation are attributable to Allergan?
- 3 A. This presentation, as I'm recalling it, is a
- 4 more general presentation on opioids, and I don't believe
- 5 it lists any specific opioid products, although I may be
- 6 wrong about that.
- Q. Okay. From looking at this presentation,
- 8 though, you can't say that any of the statements in here
- 9 are attributable to Allergan; correct?
- 10 A. Well, what I would say is that the promotional
- 11 efforts of Allergan more broadly have contributed to the
- 12 kinds of statements that are in these educational
- 13 materials that have contributed to a prescribing pattern
- 14 which is not consistent with the evidence.
- 15 Q. Okay. I understand, Dr. Lembke.
- 16 My question was: This document doesn't have any
- 17 indication if the statements in it were made by Allergan
- 18 or not?
- 19 A. Well, again, what I'm trying to -- to say is to
- 20 draw a distinction between specific products and the
- 21 paradigm shift or the cultural change in medicine around
- 22 opioid prescribing, which I do believe Allergan and other
- 23 defendants had a hand in.
- Q. I understand, but that wasn't my question.
- 25 My question is: You can't tell from this

Page 292 1 Allergan, can I assume that you didn't rely upon this

- 2 presentation in reaching your Allergan-specific opinions?
- A. No, that's not correct.
- 4 Q. Okay. But you can't tell me, sitting here
- 5 today, how you relied upon this with respect to Allergan?
- A. So I relied upon this as an example of
- 7 educational materials disseminated to healthcare
- 8 providers that misrepresents the evidence around opioid
- 9 prescribing, and I detail in many places in my report how
- 10 opioid manufacturers, distributors and pharmacies
- 11 contributed to this misrepresentation of the evidence and
- 12 the oversupply that's the essence of my report.
- 13 Q. Okay. Let's move on.
- 14 You testified earlier, I believe, that you did
- 15 not conduct any type of regression analysis. I'll try to
- 16 get the language right.
- 17 You did not conduct any type of regression
- 18 analysis to isolate the impact that any opioid -- opioid
- 19 marketing by any individual defendant had on New York
- 20 prescribers; is that correct?
- 21 A. That is correct.
- Q. Okay. Am I correct that you didn't do any type
- 23 of analysis, regression or otherwise, to isolate the
- 24 impact that any opioid marketing by any individual
- 25 defendant had on the prescription levels of opioids in

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- 1 presentation whether any of the statements in it were
- 2 made by Allergan or written by Allergan?
- 3 A. Well, many of the references on many of these
- 4 slides involve organizations that received funding from
- 5 opioid Pharma so that it is possible that some of these
- 6 slides were influenced by Allergan. So I wouldn't want 7 to say for sure.
- 8 Q. It's possible, but you don't know if that's the
- 9 case; correct?
- 10 A. Well, I wouldn't want to say that Allergan
- 11 didn't influence the content. I believe that Allergan
- 12 and other opioid manufacturers did greatly influence the
- 13 content of these kinds of learning materials.
- 14 Q. Okay. Can I ask you how -- why you added this
- 15 to your relied upon list from your MDL report to your New
- 16 York report?
- I can represent to you that it's not cited
- 18 anywhere in the body of your report or in your appendix
- 19 with respect to Allergan.
- 20 A. Okay.
- 21 Q. In fact, let me withdraw my question and ask you
- 22 a different one.
- 23 A. Okay.
- 24 Q. If this presentation is not listed anywhere in
- 25 your report or in your appendix that's specific to

- 1 New York?
- A. So I read the analyses of others on specific New
- 3 York prescribing, and those are in my report, and I've
- 4 cited those in testimony. But I did not do my own
- 5 individual crunching of numbers, as it were.
- 6 O. Okav
- 7 A. I have done lots of qualitative analyses that I
- 8 do think apply to the State of New York and Suffolk and
- 9 Nassau counties.
- 10 Q. Understood. And that would mean that you
- 11 haven't done any independent analysis to try to determine
- 12 the impact of Allergan-specific promotional activity on
- 13 the levels of prescribing in Northern California or in
- 14 Suffolk County or in Nassau; correct?
- 15 A. Incorrect. I believe that I have done my own
- 16 independent analyses, as evidenced by peer-reviewed
- 17 articles I've written, as evidenced by my book, that very
- 18 carefully details the role of opioid manufacturers --
- 19 Allergan is one example -- in creating the
- 20 overprescribing and oversupply of opioids leading to the
- 21 opioid epidemic.
- That is an analysis that I did, a causal
- 23 analysis.
- Q. Okay. Have you done -- am I correct that you
- 25 have not done any quantitative analysis in order to

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1 quantify how, if at all, Allergan's promotion contributed

- 2 to the level of opioid prescribing in New York?
- A. I would respectfully disagree with that. I've
- 4 published a paper on which prescribers are prescribing
- 5 the most opioids, using a national database, Medicare
- 6 database, including prescribers in the state of New York.
- 7 And that is a quantitative analysis.
- Q. Have you done any -- do you have an opinion and
- 9 are you offering an opinion about the quantitative impact
- 10 that Allergan's opioid marketing had on prescription
- 11 levels in New York?
- A. I'm not quantifying Allergan's role, but I am
- 13 offering an opinion that Allergan contributed to
- 14 increased prescribing in the state of New York.
- 15 Q. Okay. But you haven't done any analysis to
- 16 quantify what that impact was?
- 17 A. Well, I have done a quantitative analysis in the
- 18 article that I published in JAMA looking at who is
- 19 prescribing opioids, and what we saw was no geographic
- 20 variation in that pattern across 50 states.
- 21 And I've also, as I said, done a qualitative
- 22 analysis which I believe represents the same problems in
- 23 New York as everywhere else in the country.
- Q. Am I correct, Doctor, that you don't know how
- 25 many details Allergan sales reps conducted in New York?
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- 1 A. That is correct.
- Q. And you don't know how the number of Allergan
- 3 details compares to any other defendants?
- 4 A. That is correct.
- Q. And you don't know how many prescriptions of
- 6 Allergan's opioid products there were in New York?
- 7 A. That is correct.
- Q. And you don't know what Allergan's market share
- 9 of opioid prescriptions was in New York; is that right?
- 10 A. That is correct.
- 11 Q. And am I correct that you cannot name any
- 12 individual doctor in New York that wrote a prescription
- 13 for an Allergan opioid that they would not have otherwise
- 14 written because of Allergan's promotional marketing?
- 15 MR. ARBITBLIT: Object to form.
- THE WITNESS: Again, my prior answer regarding
- 17 the overall influence of the opioid industry on
- 18 overprescribing of opioids does apply to New York as
- 19 well.
- 20 Q. BY MS. RIVERA: But you cannot identify a
- 21 specific doctor in New York that wrote a prescription as
- 22 a result of Allergan's promotional activity; correct?
- 23 A. I have spoken to doctors who practice in New
- 24 York who communicated to me that they were influenced by 24 level of opioid prescriptions, does it?
- 25 the misleading of the opioid pharmaceutical industry, but

1 not at the level of specificity of naming specific opioid

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- manufacturers.
- Q. Can you identify a specific individual who died
- 4 or overdosed in New York as a result of taking an
- 5 Allergan opioid?
- A. Same -- same answer as the last question.
- Q. Can you answer it for me more specifically to
- 8 this question? Can you identify a specific individual
- 9 who died or overdosed in New York, Suffolk County or
- 10 Nassau County, as a result of taking an Allergan opioid?
- 11 MR. ARBITBLIT: Object to form.
- 12 THE WITNESS: Not by name.
- Q. BY MS. RIVERA: Can you identify any individual
- 14 in New York who became addicted to any opioid or misused
- 15 any opioid as a result of taking an Allergan opioid
- 16 product in New York?
- 17 A. Not by name.
- 18 Q. Can you identify any individual description in
- 19 New York, Suffolk County or Nassau County, of an Allergan
- 20 opioid that was medically inappropriate?
- 21 A. Not by name.
- 22 Q. Just a few more questions.
- 23 Based on your experience, Doctor, would you
- 24 agree that sometimes manufacturers will detail physicians
- 25 for the specific purpose of trying to promote
- - 1 substitution of one opioid for another opioid?
 - 2 MR. ARBITBLIT: Object to form.
 - 3 THE WITNESS: Can you rephrase your question?
 - 4 Q. BY MS. RIVERA: Sure.
 - 5 In other words, are you familiar that -- with
 - 6 the fact that manufacturers may detail physicians in
 - 7 order to try to convince them to switch from one opioid
 - 8 to another opioid?
 - 9 A. Yes.
- 10 Q. Okay. And if that detailing is successful and
- 11 the doctor switches from one opioid to another opioid,
- 12 that is not increase in the overall level of opioid
- 13 prescriptions, is it?
- 14 MR. ARBITBLIT: Object to form.
- 15 THE WITNESS: It really depends on whether or
- 16 not that switch, which is most commonly done to try to
- 17 overcome tolerance, actually leads to an increase in the
- 18 total of morphine milligram equivalence of that opioid,
- which is one way to measure increase in supply.
- 20 Q. BY MS. RIVERA: Okay. And if it doesn't lead to 21 an increase in the total morphine milligrams and it's
- 22 just switching the same level of milligrams from one
- 23 opioid to another, that does not increase the overall
- 25 MR. ARBITBLIT: Object to form.

Page 298 Page 300 THE WITNESS: Well, it might do if it leads to Q. Okay. Three more quick questions. 1 1 2 more prolonged exposure to that opioid as a result of the 2 Can you identify any payments to a KOL by 3 switch. So not only had the last three decades been 3 Allergan? 4 characterized by increasing doses of opioids, but also A. Well, this \$50,000, if I could verify that, 5 increasing duration. More than 80 percent of individuals 5 would serve. 6 receiving opioid therapy are on long-term opioid therapy Q. Okay. Other than that. And that's not a KOL; 7 despite the absence of evidence for long-term use. 7 right? Q. BY MS. RIVERA: Okay. Let me hand you what's 8 A. Well, it's founded and led by Dahl and Joranson, 9 who are definitely KOLs. 9 been marked as Exhibit 14 very quickly (indicating). 10 MR. ARBITBLIT: Copy, please. 10 Q. Let me try it again. 11 MS. RIVERA: Oh, sorry. 11 If you look at pages 19 to 22 of your report 12 Q. In your Appendix 2, you identify some documents 12 where you discuss KOLs that are sponsored by 13 that you believe support that manufacturers supported the 13 manufacturers --14 Wisconsin Pain and Policy Study Group? 14 A. Uh-huh. 15 Q. -- you don't see any reference to Allergan 15 A. Yes. 16 there, do you? 16 Q. Okay. And I'll represent to you that the 17 document that you cited with respect to Allergan and 17 A. No. I'm not seeing any other reference. 18 Actavis is the document that I just handed you as 18 MS. RIVERA: Okay. That's all I have. Pass the 19 Exhibit 14. 19 witness. 20 20 And you can see that -- sorry, on page 5 of your Off the record, yes, please. 21 Appendix 2, paragraph 22 also page 5 of the Pain and 21 THE VIDEOGRAPHER: Going off the record, the 22 Policy Study Group appendix? 22 time is 5:07 p.m. 23 23 A. Yep. (Discussion off the record.) 24 Q. Paragraph 22? 24 THE VIDEOGRAPHER: Back on the record, the time 25 A. Yep. 25 is 5:09 p.m. Page 299 Page 301 1 Q. Okay. And so this is the document that you **EXAMINATION** 2 cited to support that Allergan or Actavis had supported Q. BY MS. LEIBELL: Good afternoon, Dr. Lembke. My 3 that Pain and Policy Group. I'll represent to you that 3 name is Martha Leibell and I represent Teva 4 there is no mention of Allergan or Actavis in this 4 Pharmaceuticals USA, Inc., Cephalon, Inc., Actavis, LLC, 5 document. 5 Actavis Pharma, Inc., and Watson Laboratories, Inc., in If that's the case, do you have any other 6 the current litigation. 7 evidence that you're aware of that would suggest that Can you tell me what medicines Actavis, LLC 8 Allergan or Actavis supported the Wisconsin Pain and 8 manufactures or sells? 9 Policy Group, that's not cited in your appendix? A. Yes. Is Actavis a subsidiary of Teva? A. If I cited it in the appendix I would -- and 10 Q. It is a separate entity. I'm asking only about 11 it's not appearing in this document, I would really want 11 Actavis LLC 12 to go back and see what I was referring to. 12 A. I believe that all of the opioid manufacturers, Q. Okay. As you sit here today, though, you don't 13 the defendants in this litigation, have manufactured some 14 have any other evidence that Allergan supported the Pain 14 form, either branded or generic hydrocodone and 15 and Policy Group; correct? 15 oxycodone 16 MR. ARBITBLIT: Object to form. Q. Okay. And is it the same answer for Actavis 16 17 THE WITNESS: So I am not intimately familiar 17 Pharma, Inc.? 18 with the various Allergan subsidiaries or predecessors. 18 A. Yes, same answer for Actavis Pharma, Inc. 19 So I wouldn't want to make that kind of global statement 19 Q. And same question for Watson Laboratories, Inc.? 20 without double-checking the source and also verify that 20 A. Yes, I believe so. 21 there's not some subsidiary that did contribute. 21 Q. Did you review any package inserts or labels for Q. BY MS. RIVERA: Okay. But as you sit here 22 any of the medicines those three entities manufacture or 23 today, you don't have any other evidence that you can 23 sell? 24 point to; correct? 24 A. In my career, I have reviewed package inserts 25 A. Not right now. 25 for many different opioids, and I'm sure that has

Page 302 1 included products that your defendant client sells.

- 2 Q. For purposes of preparing for the instant
- 3 litigation, have you reviewed any package inserts for any
- 4 drugs manufactured or sold by those three entities?
- A. No.
- 6 Q. In Appendix 1 to your report, you do not
- 7 identify any promotional materials published by Actavis,
- 8 LLC, Actavis Pharma, Inc., or Watson Laboratories, Inc.;
- 9 correct?
- 10 A. Correct.
- 11 Q. Are you aware that these three entities
- 12 manufacture and/or sell generic opioid medicines?
- 13 A. Yes
- 14 Q. Are you aware that generic opioid medicines are
- 15 not marketed or promoted other than informing the public
- 16 of availability and pricing?
- 17 MR. ARBITBLIT: Object to form.
- 18 THE WITNESS: I'm aware of that, but I would add
- 19 that marketing for branded products influenced the
- 20 prescribing and supply of generic products, and in that
- 21 sense, the result is effectively the same for branded and
- 22 generic products.
- 23 Q. BY MS. LEIBELL: Are you aware of a single
- 24 person in Nassau County that was harmed as a result of a
- 25 medically inappropriate generic opioid prescription

- 1 A. Oh. Yes, I do know what that is.
- 2 Q. Okay.
- A. I have not heard it referred to as a TIRF
- 4 medicine.
- 5 Q. Are you aware that they are both -- Actiq and

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- 6 Fentora are both short-acting opioids indicated for
- 7 breakthrough cancer pain in opioid-tolerant patients?
- 8 A. Yes, I'm aware of that, but I will say that in
- 9 my clinical experience, I've seen many patients who don't
- 10 fit that description, who have been on Actiq and Fentora.
- 11 Q. Have you yourself ever prescribed a TIRF
- 12 medicine?
- 13 A. I don't recall doing so, but I may have done
- 14 very early in my career when I was still in training. I
- 15 certainly have not done so in the last 20 years.
- 16 I have, however, treated many patients who have
- 17 been on Actiq and Fentora. As I stated previously in the
- 18 deposition, I was shocked to see patients coming into my
- 19 office sucking on fentanyl lollipops.
- 20 Q. Have you ever prescribed a medication for
- 21 off-label use?

24

- A. Yes, I have.
- Q. Do you know what the TIRF REMS program is?
 - A. Yes, I do.
- Q. Can you tell me what that stands for?

- 1 manufactured or sold by these three entities?
- 2 MR. ARBITBLIT: Object to form.
- 3 THE WITNESS: Not by name.
- 4 Q. BY MS. LEIBELL: Same question for Suffolk
- 5 County.
- 6 A. Not by name. And I would also refer you back to
- 7 my answer to similar questions from other defendants just
- 8 regarding the overall influence of opioid manufacturers,
- 9 distributors and pharmacies in increasing the supply,
- 10 which also apply to these questions here.
- 11 Q. Thank you. I was paying close attention all
- 12 day, but I am asking questions specifically about my
- 13 clients.
- 14 And are you aware of a single person in New York
- 15 state that was harmed as a result of a medically
- 16 inappropriate generic opioid prescription manufactured or
- 17 sold by the three entities I mentioned?
- 18 A. Not by name.
- $19\,$ $\,$ Q. Are you aware that Actiq and Fentora are TIRF
- 20 medicines?
- 21 MR. ARBITBLIT: Object to form.
- THE WITNESS: I don't know what a TIRF medicine
- 23 is.
- 24 Q. BY MS. LEIBELL: Well, I can represent that that
- 25 stands for transmucosal immediate-release fentanyl.

- A. Well, REMS stands for Risk Evaluation and
- 2 Mitigation Strategy. And again, I've not heard this term
- 3 TIRF before, but transmucosal immediate-release
- 4 medications are associated with a very specific REMS in
- 5 order to -- that doctors are required to take as part of
- 6 their responsibility before they prescribe or as they are
- 7 prescribing these opioids.
- 8 Q. And are you aware that the TIRF REMS program was
- 9 implemented in March 2012?
- 10 MR. ARBITBLIT: Object to form.
- 11 THE WITNESS: I'm not recalling the specific
- 12 date, but that sounds about right.
- 13 Q. BY MS. LEIBELL: And are you aware that the TIRF
- 14 REMS program requires an FDA-approved medication guide to
- 15 be provided to patients before the medication is
- 16 dispensed in an outpatient setting?
- 17 A. Can you repeat the question?
- 18 Q. Sure.
- 19 Are you aware that the TIRF REMS program
- 20 requires an FDA-approved medication guide to be provided
- 21 to patients before the medicine is dispensed in an
- 22 outpatient setting?
- 23 A. I didn't remember that, but I believe you.
- Q. And do you know whether or not medication guides
- 25 usually contain product labels?

Page 306 A. I would really want to see the specific

2 medication guide before I could comment on that. I can

- 3 say that I have reviewed the REMS. I've personally
- 4 reviewed the REMS for transmucosal immediate-release
- 5 medications, and I think they're inadequate in order to
- 6 properly educate doctors about the risks and benefits of 7 opioids.
- 8 Q. In what respect are they inadequate?
- A. I think they perpetrate many of the misleading
- 10 messages along the lines of opioids being a safe and
- 11 effective treatment for chronic pain and that the risk is
- 12 relatively low.

1

- 13 They also spend very little time in general
- 14 educating prescribers on addiction, what it is, how to
- 15 screen and intervene, how to monitor patients. The
- 16 majority of the time is spent on how to initiate opioids,
- 17 how to maintain opioids, how to switch from one opioid to
- 18 another.
- 19 Q. Are you aware that prescribers are required to
- 20 certify that they understand the risks of abuse,
- 21 potential harm from these opioids?
- 22 A. Yes, I am. But I don't think that that has made
- 23 much inroads in mitigating those risks. I am familiar
- 24 with cases of individuals who engaged in a -- physicians
- 25 who engaged in egregious overprescribing, who documented 25 materials published by those two entities.
- 24
 - - Page 307
- 1 that they took these REMS, but clearly their practice was
- 2 not informed by safe opioid prescribing.
- Q. Are you aware that patients also must certify
- 4 that they've received medication guides from their
- 5 prescribers before they can be dispensed these
- 7 A. I don't remember that, but I believe you.
- Q. And are you aware that the patient form
- 9 component requires each patient prescriber to agree that
- 10 they each understand the risks, consequences, and
- 11 approved uses of TIRF medicines?
- 12 A. Thank you for telling me that. That's good to
- 13 know. I would highlight, though, a paper that just came
- 14 out in the last month by Hayward, et al., which looked at
- 15 the --
- 16 Q. I'm so sorry to stop you just because I'm very
- 17 short on time.
- A. Yes. Specifically that paper says that -- that
- 19 REMS is not showing that it's having an impact.
- 20 Q. Okay. I will turn to my next few final
- 21 questions.
- 22 In Appendix 1 to your report, you list
- 23 promotional messages that you identify as misleading and
- 24 identify certain defendants' promotional messages;
- 25 correct?

- 1 A. That is correct.
- 2 Q. Teva Pharmaceuticals USA is not one of those

- 3 defendants; correct?
- A. It is not listed in Appendix 1, that is correct.
- Q. Cephalon, Inc., is not one of those defendants
- 6 listed in Appendix 1; correct?
- A. That is correct; however, I do refer to
- 8 Cephalon, Inc., in my report when I discuss the influence
- 9 of the opioid pharmaceutical industry. I'm happy to turn 10 to that.
- 11 Q. That's okay. Would you identify -- can you tell
- 12 me --
- 13 A. Please do look at that, though, when you have a
- 14 moment because I would like that to be part of my -- my
- 15 response. And I understand you don't have much time.
- 16 Q. I have reviewed it.
- 17 A. Great.
- 18 Q. Have you identified any allegedly misleading
- 19 promotional messages that were published by Cephalon,
- 20 Inc., or Teva Pharmaceuticals USA, Inc., in preparation
- 21 for this litigation?
- A. So I have reviewed the way that Cephalon, Inc., 22
- 23 promoted guidelines and professional organizations --
 - Q. I'm asking a very specific question about
 - - Page 309
- 1 A. Have I reviewed --
 - Q. Yes. 2
 - 3 A. -- promotional materials published by those two
 - 4 entities; is that what you're asking me?
 - 5 Q. Correct. In furtherance of this litigation.

 - 7 Q. Okay. Are you aware of any prescriber in Nassau
 - 8 County who since 2012 was not aware of the risks and
 - 9 indications of Actiq or Fentora before he or she wrote an
 - 10 Actiq or Fentora prescription?
 - 11 A. Not by name, but generally, I am aware of
 - 12 prescribers in the state of New York who were influenced
 - 13 by the misleading messaging of opioid manufacturers
 - 14 regarding -- and including fentanyl lollipops.
 - 15 Q. Same question for Suffolk County and New York
 - 16 State?
 - 17 A. Yes, same answer.
 - 18 Q. Are you aware of a single person in New York
 - 19 State, Suffolk County, or Nassau County that was harmed
 - 20 as a result of a medically inappropriate Actiq or Fentora
 - 21 prescription?
 - 22 A. Not by name.
 - 23 MS. LEIBELL: Thank you, Dr. Lembke.
 - 24 Off the record.
 - 25 THE VIDEOGRAPHER: Going off the record, the

Page 310 Page 312 1 time is 5:20 p.m. Would you ever advise one of your clients that 2 they should not be reluctant to seek pain relief because 2 (Discussion off the record.) 3 THE VIDEOGRAPHER: Back on the record, the time 3 of the fear of addiction? 4 is 5:21 p.m. A. Oh, I see. I had misunderstood that previously. 5 **EXAMINATION** No, I would not advise that. I would not advise Q. BY MS. RODGERS: Good afternoon, Dr. Lembke. My 6 that. I would say that the risk of addiction is very 6 7 name is Megan Rodgers. I'm with the firm Covington & 7 appropriate and necessary when it comes to taking 8 opioids, even in the context of treatment for a medical 8 Burling, and I represent McKesson. I have just a few 9 condition. 9 questions for you today. 10 Do you agree that in the treatment of pain, true 10 Q. Do you think it's a misleading statement to say 11 that individuals should not be reluctant to seek pain 11 addiction is uncommon? MR. ARBITBLIT: Object to form. 12 relief because of the fear of addiction? THE WITNESS: What do you mean by "true 13 MR. ARBITBLIT: Object to form. 13 14 THE WITNESS: It's a confusing phraseology, but 14 addiction"? Q. BY MS. RODGERS: What do you understand that 15 to the extent that I think I understand what you're 15 16 saying, I would agree that it is a misleading statement. 16 phrase to mean? 17 Q. BY MS. RODGERS: Is that the kind of statement 17 MR. ARBITBLIT: Object to form. THE WITNESS: Well, I'm wondering why you 18 that could result in overprescribing of opioids? 18 19 qualify it with the word "true." 19 A. Yes. 20 Q. Do you agree that pain should be considered a 20 Q. BY MS. RODGERS: Let me ask it a slightly 21 different way. 21 fifth vital sign? 22 A. No. 22 Do you agree that in the treatment of pain, 23 Q. Is it a misleading statement to say that pain 23 addiction is uncommon? 24 should be a considered a fifth vital sign? 24 MR. ARBITBLIT: Object to form. 25 THE WITNESS: I disagree. 25 A. Yes. Page 311 Page 313 Q. BY MS. RODGERS: Is that a misleading statement? 1 Q. And is that the kind of statement that could 1 2 A. Yes, it is. 2 result in overprescribing of opioid analgesics? 3 Q. Is that the kind of statement that could result 3 A. Yes. 4 in overprescribing of opioid analgesics? 4 Q. Last few questions. Do you agree that tolerance and physical A. Yes, it is. Q. Do you agree that individuals should not be 6 dependency may be pharmacological effects of sustained 7 reluctant to seek pain behalf because of the fear of 7 use of opioid analgesics and are not synonymous with 8 addiction? 8 addiction? 9 9 MR. ARBITBLIT: Object to the form. MR. ARBITBLIT: Object to form. 10 10 THE WITNESS: Not -- can you rephrase that? THE WITNESS: As currently defined, I would 11 Sorry, end of the day, and it sort of has a double 11 agree with that statement, but whether neurobiologically 12 negative in it. 12 those are distinct phenomenon I think is uncertain. They 13 Q. BY MS. RODGERS: Sure. 13 are certainly neurobiologically related and also 14 Do you agree that individuals should not be 14 phenomenologically related. 15 reluctant to seen pain relief because of the fear of 15 Q. BY MS. RODGERS: Is that the kind of statement, 16 addiction? 16 and I'll repeat it: Tolerance and physical dependency 17 A. Yes. 17 may be pharmacological effects of sustained use of opioid Q. Is it a misleading statement to say that 18 analgesics and are not synonymous with addiction. Is 19 individuals should not be reluctant to seek pain relief 19 that the kind of statement that could result in 20 because of the fear of addiction? 20 overprescribing of opioid analgesics? 21 MR. ARBITBLIT: Object to form. 21 A. Yes. 22 THE WITNESS: I'm having a little trouble 22 MS. RODGERS: Thank you. I have no further 23 with -- I realize I'm having a little bit of trouble 23 questions. 24 tracking that statement. Can you rephrase it? 24 MR. ARBITBLIT: All right. So before we go off

25 the record, we have one little item that we want to

Q. BY MS. RODGERS: Let me ask it again.

25

	Page 314	Page 316
1	potentially correct having to do with the document	1 STATE OF CALIFORNIA) ss:
	produced natively as I believe, what was it, Exhibit 13,	2 COUNTY OF MARIN)
	that was not the same document that was referenced in the	3
4	expert's report, which does, in fact, mention funding	4 I, LESLIE ROCKWOOD ROSAS, RPR, CSR NO. 3462, do
6	And so to the extent that the document was not	5 hereby certify: 6 That the foregoing deposition testimony was
	the same as the one that the witness referenced, we would	
7	· · · · · · · · · · · · · · · · · · ·	7 taken before me at the time and place therein set forth
	5 1	8 and at which time the witness was administered the oath;
9	And we have no it's Exhibit 14. We have no	9 That testimony of the witness and all objections
	questions of the witness, but we reserve our right to	10 made by counsel at the time of the examination were
11	strike that testimony based on the wrong document.	11 recorded stenographically by me, and were thereafter
12	MR. CARTER: Doctor, are you going to read and	12 transcribed under my direction and supervision, and that
	sign?	13 the foregoing pages contain a full, true and accurate
14	MR. ARBITBLIT: What's the practice?	14 record of all proceedings and testimony to the best of my
15	MR. CARTER: I'm asking her if she's going to	15 skill and ability.
16	read and sign.	16 I further certify that I am neither counsel for
17	MR. ARBITBLIT: Well, we'll take it up. We're	17 any party to said action, nor am I related to any party
18	off the record.	18 to said action, nor am I in any way interested in the
19	THE VIDEOGRAPHER: This concludes today's	19 outcome thereof.
20	videotaped deposition of Dr. Anna Lembke. We're off the	20 IN WITNESS WHEREOF, I have subscribed my name
21	record at 5:27 p.m.	21 this 20th day of January, 2020.
22	Thank you.	22
23	(Time noted: 5:27 p.m.)	23
24	oOo	24
25		25 LESLIE ROCKWOOD ROSAS, RPR, CSR NO. 3462
4 5 6 7 8 9		
14		
15		
16		
18		
21		
21	ANNA LEMBKE, M.D.	
22	THAT BENDAE, M.D.	
	SUBSCRIBED AND SWORN TO BEFORE ME	
23	THIS DAY OF, 20	
24		
25	(NOTARY PUBLIC) MY COMMISSION EXPIRES:	

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Civil Practice Law and Rules

Article 31 Disclosure, Section 3116

(a) Signing. The deposition shall be submitted to the witness for examination and shall be read to or by him or her, and any changes in form or substance which the witness desires to make shall be entered at the end of the deposition with a statement of the reasons given by the witness for making them. The deposition shall then be signed by the witness before any officer authorized to administer an oath. If the witness fails to sign and return the deposition within sixty days, it may be used as fully as though signed. No changes to the transcript may be made by the witness more than sixty days after submission to the witness for examination.

DISCLAIMER: THE FOREGOING CIVIL PROCEDURE RULES

ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1,

2019. PLEASE REFER TO THE APPLICABLE STATE RULES

OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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